Generate Collection

L56: Entry 1 of 3 File: USPT Feb 2, 1993

DOCUMENT-IDENTIFIER: US 5183460 A
TITLE: Wound dressing retention apparatus

Brief Summary Paragraph Right (3):
Among those patents listed above, the patent to James, U.S. Pat. No. 1,615,945, is the only patent which relates a bandage to be used on the penis. The James bandage, which is referred to as a surgical appliance, is used for obviating certain discomforts associated with a circumcision, and for holding the prepuce while undergoing healing after circumcision. In general, the James surgical appliance is comprised of a girdle, an absorbent and medicated pad, and a binding strip of antiseptic gauze.

Brief Summary Paragraph Right (4):
In the patent to Imonti, U.S. Pat. No. 4,870,977, a surgical protector for raised wounds is disclosed. The surgical protector is specifically designed to protect an areola and/or nipple area of a woman's breast following a radical mastectomy. The surgical protector includes a con-shaped protector secured to a sterile pad. An adhesive system secures the pad and protector over the raised wound.

L2 ANSWER 1 OF 10 IFIPAT COPYRIGHT 2002 IFI DUPLICATE 1
AN 10115280 IFIPAT;IFIUDB;IFICDB
TI CYTOLOGICAL EVALUATION OF BREAST DUCT EPITHELIAL CELLS RETRIEVED BY DUCTAL LAVAGE
INF Chew; Karen, San Mateo, CA, US
Ljung; Britt-Marie, San Francisco, CA, US
Soito; Angela, Foster City, CA, US
IN Chew Karen; Ljung Britt-Marie; Soito Angela
PAF Unassigned
PA Unassigned Or Assigned To Individual (68000)
AG BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001, US
PI US 2002058887 A1 20020516
AI US 2001-916647 20010730
PRAI US 2000-221864 20000728 (Provisional)
FI US 2002058887 20020516
DT Utility; Patent Application - First Publication
FS MECHANICAL
FS APPLICATION
CLMN 25
2 Figure(s).
FIG. 1 illustrates a tool for accessing a breast duct according to the present invention; and
FIG. 2 illustrates a chart according to the present invention.

L2 ANSWER 2 OF 10 IFIPAT COPYRIGHT 2002 IFI DUPLICATE 2
AN 10101596 IFIPAT;IFIUDB;IFICDB
TI IDENTIFICATION OF VIRAL AGENTS IN BREAST DUCTS AND ANTIVIRAL THERAPY THEREFORE
INF Hung; David, Belmont, CA, US
IN Hung David
PAF Unassigned
PA Unassigned Or Assigned To Individual (68000)
AG BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001, US
PI US 2002045162 A1 20020418
AI US 2001-923791 20010808
PRAI US 2000-223857 20000808 (Provisional)
FI US 2002045162 20020418
DT Utility; Patent Application - First Publication
FS CHEMICAL
FS APPLICATION
CLMN 22
2 Figure(s).
FIG. 1 illustrates a tool for accessing a breast duct according to the present invention; and
FIG. 2 illustrates instructions according to the present invention.

L2 ANSWER 3 OF 10 IFIPAT COPYRIGHT 2002 IFI DUPLICATE 3
AN 10093699 IFIPAT;IFIUDB;IFICDB
TI PREPARATION FOR BREAST DUCT FLUID COLLECTION
INF Hung; David, Belmont, CA, US
Patel; Tina, San Carlos, CA, US
IN Hung David; Patel Tina
PAF Unassigned
PA Unassigned Or Assigned To Individual (68000)
AG BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001, US

PI US 2002037265 A1 20020328
AI US 2001-876144 20010608
PRAI US 2000-210438 20000608 (Provisional)
  US 2000-236506 20000929 (Provisional)
  US 2000-252090 20001121 (Provisional)
FI US 2002037265 20020328
DT Utility; Patent Application - First Publication
FS CHEMICAL
FS APPLICATION
CLMN 11
  3 Figure(s).
    FIG. 1 is a cross-sectional view of a nipple, lactiferous sinus, ductal network, and human breast. The ductal orifice on the nipple surface can be contacted with a probe-like member having a composition coating its tip that transfers some of the composition to the ductal orifice.
    FIG. 2 is a cross-sectional view of a nipple, lactiferous sinus, ductal network and human breast being accessed with a ductal access device. The figure depicts infusion of a liquid into the duct from the lumen of the ductal access device.
    FIG. 3 is a cross-sectional view of a nipple, lactiferous sinus, ductal network and human breast being accessed with a ductal access device. The device has infused fluid and has nearly filled the duct from a position distal to the ductal sphincter of the lactiferous sinus.

L2 ANSWER 4 OF 10 IFIPAT COPYRIGHT 2002 IFI DUPLICATE 4
AN 10063589 IFIPAT;IFIUDB;IFICDB
TI METHOD FOR DIFFERENTIATING BREAST DUCTS FOR CANCER RISK STATUS
INF Hung; David, Belmont, CA, US
  Love; Susan, Pacific Palisades, CA, US
IN Hung David; Love Susan
PAF Unassigned
PA Unassigned Or Assigned To Individual (68000)
AG BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001, US
PI US 2002007115 A1 20020117
AI US 2001-852145 20010510
PRAI US 2000-203416 20000510 (Provisional)
  US 2001-289536 20010509 (Provisional)
FI US 2002007115 20020117
DT Utility; Patent Application - First Publication
FS MECHANICAL
FS APPLICATION
CLMN 32

L2 ANSWER 5 OF 10 USPATFULL
AN 2002:17522 USPATFULL
TI Devices, methods and systems for collecting material from a breast duct
IN Hung, David, Belmont, CA, UNITED STATES
  Ken, Christopher G.M., San Mateo, CA, UNITED STATES
  He, Xuanmin, Palo Alto, CA, UNITED STATES
  Olsen, Phillip M., Mountain View, CA, UNITED STATES
  Nikolchev, Julian, Portola Valley, CA, UNITED STATES
  O'Leary, Shawn, San Jose, CA, UNITED STATES
  Sayavong, Pam, Newark, CA, UNITED STATES
PI US 2002010405 A1 20020124
AI US 2001-907931 A1 20010719 (9)
RLI Division of Ser. No. US 1999-473510, filed on 28 Dec 1999, PENDING
PRAI US 1998-114048P 19981228 (60)
  US 1999-134613P 19990518 (60)

```
       US 1999-143476P     19990712 (60)
       US 1999-143359P     19990712 (60)
       US 1999-170997P     19991214 (60)
DT     Utility
FS     APPLICATION
LREP   BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001
CLMN   Number of Claims: 165
ECL    Exemplary Claim: 1
DRWN   12 Drawing Page(s)
LN.CNT 2866

L2   ANSWER 6 OF 10  USPATFULL
AN     2002:4362  USPATFULL
TI     Devices, methods and systems for collecting material from a breast duct
IN     Hung, David, Belmont, CA, UNITED STATES
       Ken, Christopher G.M., San Mateo, CA, UNITED STATES
       He, Xuanmin, Palo Alto, CA, UNITED STATES
       Olsen, Phillip M., Mountain View, CA, UNITED STATES
       Nikolchev, Julian, Portola Valley, CA, UNITED STATES
       O'Leary, Shawn, San Jose, CA, UNITED STATES
       Sayavong, Pam, Newark, CA, UNITED STATES
PI     US 2002002343       A1   20020103
AI     US 2001-907581      A1   20010719 (9)
RLI    Division of Ser. No. US 1999-473510, filed on 28 Dec 1999, PENDING
PRAI   US 1998-114048P     19981228 (60)
       US 1999-134613P     19990518 (60)
       US 1999-143476P     19990712 (60)
       US 1999-143359P     19990712 (60)
       US 1999-170997P     19991214 (60)
DT     Utility
FS     APPLICATION
LREP   BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001
CLMN   Number of Claims: 165
ECL    Exemplary Claim: 1
DRWN   12 Drawing Page(s)
LN.CNT 2859

L2   ANSWER 7 OF 10  USPATFULL
AN     2002:160110  USPATFULL
TI     Devices, methods and systems for collecting material from a breast duct
IN     Hung, David, Belmont, CA, United States
       Ken, Christopher G. M., San Mateo, CA, United States
       He, Xuanmin, Palo Alto, CA, United States
       Olsen, Phillip M., Mountain View, CA, United States
       Nikolchev, Julian, Portola Valley, CA, United States
       O'Leary, Shawn, San Jose, CA, United States
       Sayavong, Pam, Newark, CA, United States
PA     Pro Duct Health, Inc., Menlo Park, CA, United States (U.S. corporation)
PI     US 6413228          B1   20020702
AI     US 1999-473510           19991228 (9)
PRAI   US 1998-114048P     19981228 (60)
       US 1999-134613P     19990518 (60)
       US 1999-143359P     19990712 (60)
       US 1999-170997P     19991214 (60)
DT     Utility
FS     GRANTED
EXNAM  Primary Examiner: Winakur, Eric F.; Assistant Examiner: Marmor, II,
       Charles
LREP   Banner & Witcoff, Ltd.
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CLMN Number of Claims: 101
ECL Exemplary Claim: 1
DRWN 18 Drawing Figure(s); 12 Drawing Page(s)
LN.CNT 2654
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L2 ANSWER 8 OF 10 USPATFULL
AN 2002:115555 USPATFULL
TI Methods and systems for treating breast tissue
IN Hung, David, Belmont, CA, United States
Ken, Chris, San Mateo, CA, United States
Nikolchev, Julian, Portola Valley, CA, United States
Love, Susan, Pacific Palisades, CA, United States
O'Leary, Shawn, San Jose, CA, United States
PA Pro Duct Health, Inc., Menlo Park, CA, United States (U.S. corporation)
PI US 6391026 B1 20020521
AI US 1999-397753 19990916 (9)
PRAI US 1998-100853P 19980918 (60)
DT Utility
FS GRANTED
EXNAM Primary Examiner: Kearney, R.
LREP Banner & Witcoff, Ltd.
CLMN Number of Claims: 55
ECL Exemplary Claim: 1
DRWN 20 Drawing Figure(s); 12 Drawing Page(s)
LN.CNT 1127

L2 ANSWER 9 OF 10 USPATFULL
AN 2001:188406 USPATFULL
TI Isolated ductal fluid sample
IN Hung, David, Belmont, CA, United States
PI US 2001034038 A1 20011025
AI US 2001-800970 A1 20010308 (9)
RLI Continuation-in-part of Ser. No. US 2000-625399, filed on 26 Jul 2000, PENDING Continuation-in-part of Ser. No. US 2000-502404, filed on 10 Feb
2000, PENDING Continuation-in-part of Ser. No. US 1999-313463, filed on 17 May 1999, ABANDONED Continuation-in-part of Ser. No. US 1999-473510, filed on 28 Dec 1999, PENDING
PRAI US 1999-166100P 19991117 (60)
DT Utility
FS APPLICATION
LREP BANNER & WITCOFF, 1001 G STREET N W, SUITE 1100, WASHINGTON, DC, 20001
CLMN Number of Claims: 30
ECL Exemplary Claim: 1
DRWN No Drawings
LN.CNT 1129
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L2 ANSWER 10 OF 10 USPATFULL
AN 2001:225998 USPATFULL
TI Devices and methods to identify ductal orifices during nipple aspiration
IN Hung, David, Belmont, CA, United States
Love, Susan M., Pacific Palisades, CA, United States
Nikolchev, Julian, Portola Valley, CA, United States
George, William R., Santz Cruz, CA, United States
PA Pro Duct Health, Inc., Menlo Park, CA, United States (U.S. corporation)
PI US 6328709 B1 20011211

AI US 1999-438219 19991112 (9)
PRAI US 1998-108449P 19981113 (60)
US 1999-127507P 19990402 (60)
DT Utility
FS GRANTED
EXNAM Primary Examiner: Nguyen, Anhtuan T.
LREP Banner & Witcoff, Ltd.
CLMN Number of Claims: 18
ECL Exemplary Claim: 1
DRWN 8 Drawing Figure(s); 7 Drawing Page(s)
LN.CNT 1195

=>

L18 ANSWER 9 OF 13 USPATFULL
AN 2001:1467 USPATFULL
TI Methods and kits for identifying ductal orifices
IN Barsky, Sanford H., Los Angeles, CA, United States
Love, Susan M., Pacific Palisades, CA, United States
PA The Regents of the University of California, Oakland, CA, United States (U.S. corporation)
PI US 6168779 B1 20010102
AI US 1997-931786 19970916 (8)
DT Utility
FS Granted
EXNAM Primary Examiner: Housel, James C.; Assistant Examiner: Devi, S.
LREP Gates & Cooper
CLMN Number of Claims: 27
ECL Exemplary Claim: 1
DRWN 4 Drawing Figure(s); 4 Drawing Page(s)
LN.CNT 544

L18 ANSWER 10 OF 13 CANCERLIT DUPLICATE 1
AN 1998074321 CANCERLIT
DN 98074321
TI Preoperative methylene blue staining of galactographically suspicious **breast** lesions.
AU Saarela A O; Kiviniemi H O; Rissanen T J
CS Department of Surgery, Oulu University Hospital, Finland.
SO INTERNATIONAL SURGERY, (1997). Vol. 82, No. 4, pp. 403-5.
Journal code: GUP. ISSN: 0020-8868.
DT Journal; Article; (JOURNAL ARTICLE)
FS MEDL; L; Priority Journals
LA English
OS MEDLINE 98074321
EM 199802

L18 ANSWER 11 OF 13 CANCERLIT DUPLICATE 2
AN 96408110 CANCERLIT
DN 96408110
TI Ductography is a useful technique in evaluation of abnormal **nipple** discharge.
AU Rongione A J; Evans B D; Kling K M; McFadden D W
CS Department of Surgery, UCLA Medical Center, and Sepulveda Veterans Affairs
Medical Center, Los Angeles, California 90024, USA.
SO AMERICAN SURGEON, (1996). Vol. 62, No. 10, pp. 785-8.
Journal code: 43E. ISSN: 0003-1348.
DT Journal; Article; (JOURNAL ARTICLE)
FS MEDL; L; Priority Journals
LA English
OS MEDLINE 96408110
EM 199612

L18 ANSWER 12 OF 13 EMBASE COPYRIGHT 2002 ELSEVIER SCI. B.V.
AN 96219730 EMBASE
DN 1996219730
TI [Selective galactophorectomy: More than 350 cases treated].
LA GALATTOFORECTOMIA SELETTIVA: PERSONALE ESPERIENZA CHIRURGICA IN OLTRE 350 INTERVENTI.
AU Martini Z.
CS Divisione di Chirurgia Plastica, Ospedale Civile di Vincenza,Vincenza,

09/876144

Italy
SO Rivista Italiana di Chirurgia Plastica, (1996) 28/2 (179-185).
ISSN: 0391-2221 CODEN: RIPLDG
CY Italy
DT Journal; Article
FS 009 Surgery
016 Cancer
LA Italian
SL English; Italian

L18 ANSWER 13 OF 13 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.DUPLICATE 3
AN 1984:235832 BIOSIS
DN BA77:68816
TI **GALACTOGRAPHY** THE DIAGNOSTIC PROCEDURE OF CHOICE FOR **NIPPLE** DISCHARGE.
AU TABAR L; DEAN P B; PENTEK Z
CS MAMMOGRAPHY DEP., FALUN CENT. HOSP., 791 82 FALUN, SWEDEN.
SO RADIOLOGY, (1983) 149 (1), 31-38.
CODEN: RADLAX. ISSN: 0033-8419.
FS BA; OLD
LA English

=> d l18 7-13 kwic

L18 ANSWER 7 OF 13 USPATFULL
TI Apparatus, methods and kits for simultaneous delivery of a substance to multiple **breast** milk ducts
AB Apparatus, methods and kits for simultaneous delivery of a fluid or other substance to two or more **breast** milk ducts are provided. The fluid can be delivered for a variety of purposes including lavage of the ducts and. . .
SUMM . . . generally to medical devices and methods. More particularly, it relates to devices and methods for the delivery of substances to **breast** milk ducts.
SUMM The current state of the ductal access art is that the ducts in a **breast** are accessed one-by-one with a catheter. The human **breast** has from 6-12 ducts. This process of duct-by-duct access has many disadvantages, including that the process is slow and that it is very difficult after finishing lavage of one duct to know which of the other ducts of a **breast** have or have not been lavaged. Thus, under the one-duct-at-a-time duct lavaging or accessing system it is easy to miss. . .
SUMM . . . including methods described in Love and Barsky, (1996) Lancet 348: 997-999, and presentations about ductal access made in Love, (1992) "**Breast** duct endoscopy: a pilot study of potential technique for evaluating **intraductal** disease," presented at 15th Annual San Antonio **Breast** Cancer Symposium, San Antonio, Tex., Abstract 197; Barsky and Love (1996) "Pathological analysis of **breast** duct endoscoped mastectomies," Laboratory Investigation, Modern Pathology, Abstract 67; and Lewis (1997) Biophotonics International, pages 27-28, May/June 1997.
SUMM A company called Diagnostics, Inc. formed in 1968, produced devices to obtain **breast** ductal fluid for cytological evaluation. The

devices included a **breast** duct catheter to infuse fluid into and collect fluid from individual ducts. The devices were sold prior to May 28, 1976 for the purpose of collecting **breast** ductal fluid for cytological evaluation.

SUMM A patent application entitled "Methods and kits for obtaining fluid and cellular material from **breast** ducts," U.S. Ser. No. 09/067,661 filed Apr. 28, 1998, and its continuation-in-part, U.S. Ser. No. 09/301,058 filed Apr. 28, 1999,. . . 1999, and non-provisional application No. 09/473,510, filed Dec. 28, 1999 describe methods and apparatus for delivering a substance to a **breast** duct.

SUMM Apparatus for accessing two or more ductal networks in a **breast** comprise two or more individual access probes, each probe having a lumen and being configured for insertion through an orifice. . .

SUMM . . . or connectable to the probe lumen. Thus is provided an apparatus for accessing a plurality of ductal networks in a **breast**, comprising a plurality of individual access probes, each probe having a lumen and being configured for insertion through an orifice. . .

SUMM A method for delivering a substance to two or more ductal networks in a **breast** is provided comprising establishing access to two or more ductal network in the **breast** through a ductal orifice of each ductal network; and thereafter delivering a substance to and/or collecting a fluid from two. . . in separate receptacles for each ductal network. The access can be established to each of the ductal networks in a **breast**.

SUMM A method for delivering a fluid to two or more ductal networks in a **breast** is provided comprising locating two or more ductal networks in a **nipple** of the **breast**; inserting an access probe through an orifice of each of the located ductal networks; and infusing the fluid through a. . .

SUMM A kit for delivering a substance to a two or more of ductal networks in a **breast**, is provided comprising two or more of probes each having a lumen and being configured for introduction into a ductal network of the **breast**, and instructions for use setting forth a method according to any of claims identified herein. A kit is also provided. . . outlets on the manifold. The access probes are configured for insertion through an orifice of a ductal network of a **breast**. The kit can further comprise a separate collection receptacle for each probe.

DRWD FIG. 3 shows a basic multiple duct infusion and collection apparatus accessing multiple **breast** ducts of a **breast**.

DETD Apparatus according to the present invention for accessing two or more ductal networks in a human **breast** comprises a manifold having two or more outflow ports connected or connectable to probes, catheters or other like members having lumens, each capable of accessing a **breast** duct and configured to infuse and optionally collect fluid or other infusible material into accessed **breast** ducts in a human **breast**. The manifold has an inlet for receiving fluid from a connectable fluid source, such as a pump or syringe, and. . . connect 12 or more probes in order to access and infuse all of the average 9-12 ducts in a human **breast**. Optionally, the probes may be removably attached to the manifold outlets. Thus, depending on the number of ducts to be. . .

DETD . . . ducts. The probe lumens might also be selectively closed after the ducts have been filled during a massaging of the **breast**, in order to retain fluid in the ducts and not allow it to flow back into

the infusion lumens of. . .

DETD . . . to the fluid collection receptacles. Thus the apparatus can be used for accessing a plurality of ductal networks in a **breast** with a plurality of individual access probes, each probe having a lumen and being configured for insertion through an orifice. . .

DETD . . . inside the signal sphincter and holds the lumen in place, or a wire or tether from the lumen to the **breast** skin to be held with an adhesive or other temporary anchor. Other means can be designed into the probe units. . .

DETD . . . 38 will allow the user to selectively isolate individual probes

44 at a point between the syringe 40 and the **breast**. Such isolation is useful in at least two circumstances. First, if one or more

probes 44 are not to be. . . valve 38 may be used when it is desired to remove an infused fluid from the ductal network of the **breast** . In that case, the valves 38 would be closed, and fluid aspirated or otherwise collected through a collection tube 36. . .

DETD . . . lumen, where the lumen is used at least for introducing fluids into a plurality of ductal networks in a human **breast**, as described previously. Usually, the lumen(s) will also be used for aspirating and collecting fluids from the ductal networks. In. . .

DETD . . . ductal infusion and collection apparatus 28, described above, for delivering and collecting a wash or therapeutic fluid to a human **breast** B will be described. Tips 32 of probes 44 will be introduced through orifices of the individual ductal networks in the **breast**, as generally described in the prior copending applications which have been incorporated herein by reference. Although only two probes 44 are shown introduced to the **breast** B, it will be appreciated that a larger number of probes, usually up to the total number of orifices in any breasts (e.g. 12) may be simultaneously and/or sequentially introduced to the **breast**. Once the tips 32 of the probes 44 are introduced, they may be optionally anchored in place, e.g. using tethers. . . fluid in the ductal networks and prevent backflow of the fluid from the networks into the manifold 30. Optionally, the **breast** B may be massaged at this point in order to distribute the fluid within the ductal networks. when it is.

. at least a portion of the fluid could be removed by simply allowing it to flow out and/or pressuring the **breast** to force the fluid out.

DETD . . . syringe accesses the inlet having access to two or more outlets

and/or probe lumens that are capable of accessing a **breast** duct. The access and connection between the instrument to deliver the substance and the inlet can comprise a nested fit. . .

DETD . . . two inflow lumens and the substance passes through the inlet into each of the two inflow lumens. A typical human **breast** has from 6 to 12 milk ducts on average, and thus 6 to 12 ductal orifices. In

a procedure involving diagnostic analysis of the **breast** by analyzing the **breast** duct fluid and cells it is desirable to access all of the **breast** ducts in the **breast**. This access can be accomplished at the same time or virtually simultaneously using the apparatus of the invention (i.e. using. . .

DETD . . . opportunity to minimize the tissue stress to the patient where the steps of massaging and squeezing are applied to the **breast** , e.g. in a lavage procedure. Using the apparatus allows approximate simultaneous access and approximate simultaneous delivery of the lavage

agent to the accessed ducts; thereafter and during the infusion of lavage fluid the practitioner can massage and/or squeeze the **breast**, affecting the fluid and cell yield of all the accessed ducts in the same massaging and/or squeezing action, and thereby cutting down the amount of massaging and/or squeezing of the **breast** required for the entire procedure. Massaging and/or squeezing of a **breast** having ducts accessed in a duct-by-duct fashion, requires multiple massaging and/or squeezing applications to the **breast**, and risks the inevitable increased discomfort to the patient and potential damage to the **breast** tissue by repeated handling.

DETD . . . the rare individual who has more milk ducts than the norm. However, not all outlets need to communicate with a **breast** duct (in any given procedure), and those outlets and/or inflow lumens not in use can be capped or blocked. Thus. . . the apparatus is an inlet connected to exactly the number of operable outlets and inflow lumens as the patient has **breast** ducts, and which it is desirable to access, while unused outlets remain capped or blocked from delivering the substance or. . . of the apparatus is an inlet connected to exactly the number of outlets and/or inflow lumens as the patient has **breast** ducts that require therapeutic treatment or access for other purpose, while the unused outlets remain capped or blocked from delivering. . .

DETD . . . is useful when the apparatus or manifold has more connections to inflow lumens than the patient has ducts on her **breast**, e.g. where the manifold has 12 connections and the patient has 10 ducts, two outlet connections may be capped to. . .

DETD The distal end of each inflow lumen operably connected to the inlet and manifold at the outlets accesses a **breast** milk duct through a ductal orifice. Thus, e.g. where two ducts are accessed, two inflow lumens are connected to the inlet each at an outlet; where all the ducts, on a given **nipple** are accessed, e.g. where the particular **breast** being accessed has 8 ducts, then 8 inflow lumens are operably connected to the inlet for delivery of a substance. . .

DETD The inflow or probe lumens can be any lumen capable of transferring a substance to the **breast** duct. Thus, for example, catheters and cannulas may be inflow or probe lumens. The lumen may have multiple segments, e.g.. . .

DETD . . . dilate the ducts can accomplish access of the ducts. In the past, ductal access has generally been accomplished by placing **galactography** needles or dilators of increasing sizes into the ductal orifice to dilate the orifice to a diameter sufficient to accept the subject lumen. The state of the art has been to place a small **galactography** needle or dilator into the duct, remove it, replace it with an incrementally larger needle or dilator, remove that, and. . .

DETD . . . cannula-like member essentially constructed as described in U.S. Pat. No. 5,593,393, with adaptations and adjustments to probe and dilate a **breast** duct rather than a lacrimal duct, and the cannula can be connectable to an inflow lumen that is connected to the inlet. Thus, the apparatus may comprise inflow lumens capable of accessing, dilating and delivering a substance to the **breast** duct with a single entry. Alternatively, the pre-dilation may be accomplished with a separate tool, e.g. successively larger **galactography** needles or a single graduated duct probe, or may be accomplished by a tool integral to the inflow lumen, having. . .

DETD . . . the access member. A tether is then attached to the fastener

for tethering the member accessing a duct to the **breast** and essentially also to the duct. When the probe is accessing the duct, the fastener will be optimally located about even with or just above the **nipple** surface. The tether that attaches to the fastener portion of the probe can be anything that can attach at that point and be comfortably and securely affixed to the skin of the **breast** for anchoring the probe in the duct. Thus, the tether can be a string, line,
wire or tape, for example. The tether is affixed to the skin of the **breast** by a suitable, removable means, e.g. a tape that can adhere to skin. Attachment means on the probe can include e.g. a hook or
an eye (the hook or eye being tethered to the **breast** or other anchor). The probe may also be designed to have modalities that cause the access member to stay in the duct without tethering the member to the **breast**. Thus, e.g. the probe or access member can have ridges located below the ductal orifice, small non-puncturing barbs located below. . . may serve to keep the lumen inside the duct without the need to actually tether the access tool to the **breast**. Ridges can be placed on the lumen at the region below the orifice, or above the orifice for attaching a. . . the distal tip. When the probe has accessed the duct, the fastener holding the tether is approximately flush with the **nipple** surface and at the ductal orifice. In the tether embodiment, the tether can be affixed to the skin (of the **breast**) e.g. by tape or other adhesive to anchor each probe to the accessed duct and prevent the probe or any. . .

DETD . . . access lumens and a slidable ring or seal at each hole that allow the plate to be pushed to the **nipple** surface once all the target ducts have been accessed, thus holding the lumens in place because the lumens are anchored into the plate (e.g. by the ring or seal), and the plate once placed at the **nipple** surface remains there. Optionally, the plate can be anchored to the **nipple** surface, e.g. by a few tethers located on the plate and the tether can then be affixed by some adhesive means (e.g. tape) elsewhere to the skin
of the **breast**. The plate can have multiple holes so that the plate can accommodate a various number of access lumens at various locations on a given **nipple** surface. Thus the plate is typically constructed to meet the generic needs of any patient having a lavage procedure by. . .

DETD The apparatus for delivering a substance to the **breast** ducts can further comprise a separate collection lumen branching from the probe lumen for collecting the fluid delivered to the ducts, mixed with other ductal contents including fluid, cells and other elements in a **breast** duct, e.g. for use in a lavage procedure. The collection is positioned so as to divert fluid back flow from. . .

DETD In the case of using the apparatus for a lavage procedure of the ducts of a **breast**, other features can be added to the apparatus. For example, each collection lumen can be connected to a syringe or. . .

DETD Substances that can be delivered to the **breast** milk ducts include any substance a practitioner might desire to deliver to a **breast** duct. Such substances can include, e.g. a lavage fluid for washing the ducts, a diagnostic agent, a prophylactic agent, a. . .

DETD . . . and cellular components (e.g. including molecular species) that
can provide the basis of an analysis of the condition of the

breast milk ducts. Lavage fluid can be a saline solution, e.g. normal saline, or phosphate buffered saline (PBS), or other fluid. .

.

DETD The substance delivered to the accessed **breast** ducts can be a diagnostic agent. Such an agent can diagnose a condition including a cancer or precancer condition, including. . . hyperplasia (ADH) and low grade ductal carcinoma in situ (LG-DCIS). The agent may also have the ability to diagnose other **breast** related conditions, including, e.g. fibrotic, cyst or conditions relating to lactation. Diagnostic agents can include targeting diagnostic and therapeutic agents. . .

DETD A method of delivery of a substance to two or more ductal networks in a **breast** is provided. Access is established to two or more ductal networks in the **breast** through a ductal orifice of each ductal network. Thereafter a substance is delivered to and/or a fluid is collected from. . . collected in separate receptacles for each ductal network. Access can be established to each of the ductal networks in a **breast**, so that all the ducts on a **breast** are accessed and the agent is delivered to all of the ducts.

DETD A method for delivering a fluid to two or more ductal networks in a **breast** comprises locating two or more ductal networks in a **nipple** of the **breast**, inserting an access probe through an orifice of each of the located ductal networks; and infusing the fluid through a. . .

DETD The invention also contemplates methods of accessing two or more **breast** ducts for delivery of a substance. The substance can include e.g. therapeutic, diagnostic or prophylactic substances, or delivery of a lavage fluid and conducting a lavage procedure of the **breast** ducts. Lavage procedures include delivering a substance for washing the duct (e.g. a lavage fluid) and retrieving or collecting that. . .

DETD The methods of accessing more than one **breast** duct occur using the apparatus of the invention such that all the ducts that the practitioner desires to access are. . . the methods provides a infusion inlet for the substance to be delivered, and provides for access of more than one **breast** duct at the same time, that the delivery of the substance to the ducts occurs at the same time, or. . .

DETD . . . The substance flows into the inflow lumens through them to the accessed ducts. It is expected, anatomy of the human **breast** invariably dictating that not all ducts of the **breast** are exactly the same size or of the same capacity, that some ducts may fill faster or slower than other. . .

DETD The process of delivering a substance to more than one **breast** duct requires connecting the apparatus described above (having an inlet connected at individual outlets to more than one probe lumen each capable of accessing a **breast** milk duct) to a **breast** . For example, where the **breast** has 7 ducts and the practitioner desires to access all of them, the apparatus for accessing those ducts will have. . . probe or other tool can be accomplished by a variety of means, including e.g. a characteristic electrical signal at the **nipple** surface to indicate an orifice (see e.g. co-owned application Ser. No. 09/482,145) injecting or contacting the **nipple** with a **dye** or other substance that can be extruded from the orifices thereby identifying their location (see Ser. No. 08/931,786 filed Sep.. . . 1998), or other practical or suitable

means. Corresponding to these identification means, the practitioner may also want to dekeratinize the **nipple** surface (including most importantly removing the keratin plugs from the ductal orifices) by means of applying a dekeratinizing agent (e.g. acetic acid, empigen, or cerumenex; the **nipple** can be dekeratinized with 5%-50% acetic acid to remove keratin and other potentially blocking and contaminating substances from the ductal. . . to remove visually detectable plugs. Where it is desirable and important to identify and access all the ducts on the **nipple** surface, e.g. where a diagnostic procedure (e.g. a lavage) is being conducted, a practitioner will take care in being thorough. . .

DETD . . . have a hook or an eye or some other such means to attach a line (to the skin of the **breast**) to keep the probe from sliding out of the duct. Where the duct probe is attached to the catheter, the. . .

DETD . . . invention include methods of lavaging more than one milk duct at the same time by connecting a apparatus to the **breast** that has an inlet connected to two or more outlets that each connect to a probe or lumen capable of accessing a **breast** duct. The distal end of the probe lumens can access a milk duct through a ductal orifice. The apparatus may. . .

DETD An advantage of the methods of the invention providing simultaneous access of the **breast** ducts and retrieval of ductal fluid and cellular material is that the added steps of massaging and squeezing need only. . . done once for all the accessed ducts, thus limiting any patient discomfort or minimizing any potential tissue damage to the **breast** tissue, but requiring that a cycle of massaging and squeezing need only be conducted once per procedure per **breast**.

DETD A kit for delivering a substance to a two or more of ductal networks in a **breast** is provided, having two or more of probes each having a lumen and being configured for introduction into a ductal network of the **breast**, and instructions for use setting forth a method according to those described and exemplified herein. A kit can comprise a. . . on the manifold, wherein the access probes are configured for insertion through an orifice of a ductal network of a **breast**. The kit can further comprise a separate collection receptacle for each probe.

DETD The following table illustrates results obtainable from a lavage procedure of the right and left **breast** of a patient undergoing a diagnostic lavage procedure to identify whether a cancer or pre-cancer condition exists in any of the ducts of the patient. Single lavage procedures, are conducted for the right **breast** having 7 ducts and the left **breast** having 9 ducts

DETD
TABLE 1

Duct	Lavage **Breast**/ Fluid Delivered	Fluid Collected	Cells Collected	Diagnosis (cytology)
R-1	PBS - 20 ml	++++++	++++	scattered clusters of benign unremarkable ductal. . .

DETD . . . 2 represents a hypothetical treatment protocol of the hypothetical patient tested in Table 1. During each drag administration, the right **breast** ducts are accessed at the same time (R-2 and R-6) and the left **breast** ducts are accessed in a separated procedure also at the same time (L-3, L-4, L-5).

DETD

TABLE 2

		Repeat Frequency of diagnosis
Breast/Duct	Drug Dosage	Administration by lavage
R-2 releasing gel	tamoxifen 10 mg/in time	one weekly every 3 months
R-6	tamoxifen 10 mg/in time. . .	

DETD The ducts of the right **breast** of a patient are identified by a characteristic electrical signal and as the **nipple** surface is probed with an electrode, areas of low electrical impedance (see co-owned and co-pending application Ser. No. 09/482,145 for. . . application of acetic acid mixed with Velvacrol (50% v/w), a pharmaceutical vehicle comprising an aqueous mixture of petrolatum/mineral oil, acetyl **alcohol**, sodium laurel sulfate, cholesterol, methylparaben, butylparaben, and propylparaben. To keep the acetic acid in solution, methyl cellulose (100 mg) is pre-added to the Velvacrol (5 g). The mixture possesses a uniform pasty consistency and is applied to the **nipple** as an ointment or paste. The keratinolytic agent is typically left on the **nipple** for 24 hours or longer to remove the keratin plugs from the ductal orifices. The identified orifices are then accessed. . . a line to the probe at an eye (or loop) on the probe. The line is then affixed to the **breast** skin with an adhesive bandage that holds a line that is connected to the probe. The loop rests at about the **nipple** surface. Once all the ducts are accessed the area of the **nipple** surface thoroughly re-probed with the electrode to determine that all the ducts on that **breast** have been identified and that none have been missed. The patient has 10 ducts on the right **breast** . Collection tubes connected to the 10 outflow lumens have preservative in them.

DETD . . . dual lumens and ductal orifices is carefully observed. Fluid is collected in separate collection tubes connected to the lumens. The **breast** is then massaged and squeezed gently from the base to the areola. The syringe at the inlet is pushed to 100 ml and the **breast** is squeezed and massaged at the same time. This second fraction is collected in new collection tubes and labeled accordingly. The **breast** is squeezed and massaged again. Another 50 ml is pushed out from the syringe, meanwhile the **breast** is squeezed and massaged and a third fraction collected. A fourth aliquot of 50 ml is delivered, and the **breast** also squeezed and massaged as the fourth fraction is collected.

CLM What is claimed is:

1. An apparatus for simultaneously accessing two or more ductal networks in a **breast**, said apparatus comprising: a manifold having an inlet for receiving fluid and at least two outlets; at least two individual. . . a ductal network; and a collection tube connected to

at least one probe for receiving biological material from within the **breast**.

. . . tubes, each connected to a respective one of the at least two probes,
for receiving biological material from within the **breast**.

. . . An apparatus as in claim 18, further comprising a first device connectable to the manifold for infusing fluid within the **breast**.

. . . in claim 18, further comprising a second device connectable to the collection tube for collecting biological material from within the **breast**.

. . . wherein each collection tube comprises a second device connectable to
said collection tube for collecting biological material from within the **breast**.

. . . of said manifold outlets, and each probe being configured for insertion through an orifice of a ductal network of a **breast**.

43. An apparatus for simultaneously accessing two or more ductal networks in a **breast** for ductal lavage or other medical procedures, said apparatus comprising: a manifold having an inlet for receiving fluid and at. . .
48. An apparatus capable of simultaneously accessing two or more ductal networks in a **breast** as part of a ductal lavage or other medical procedure, said apparatus comprising: at least two access probes, each access. . . of said outlets connected to one of the probes; a device connectable to the manifold for infusing fluid within the **breast**; and a device in communication with the lumen of one of said probes for collecting biological material from within the **breast**.

L18 ANSWER 8 OF 13 USPATFULL

AB A sample for diagnosis of **breast** cancer can be prepared by isolating a ductal fluid sample from one duct of a **breast** of a patient. The isolated ductal fluid is not mixed with ductal fluid from any other duct of the **breast**. Generally the target duct is not spontaneously discharging. The isolated ductal fluid sample can be examined to determine the presence. . . with cancer or pre-cancer. An
isolated ductal fluid sample not mixed with ductal fluid from any other duct of the **breast** permits identification of the duct which is diseased and provides increased sensitivity for existing diagnostic and analytic techniques.

SUMM [0002] For several decades significant members of the medical community dedicated to studying **breast** cancer have believed and shown that the cytological analysis of cells retrieved from **nipple** discharge from the **breast** milk ducts can provide valuable information for identifying patients at risk for **breast** cancer. Papanicolaou himself contributed to the genesis of such a possibility of a "Pap" smear for **breast** cancer by analyzing the cells contained in **nipple** discharge. See Papanicolaou et al, "Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the **Breast**"

Cancer (1958) March/April 377-409. See also Petrakis, "Physiological, biochemical, and cytological aspects of **nipple** aspirate fluid", **Breast** Cancer Research and Treatment 1986; 8:7-19; Petrakis, "Studies on the epidemiology and natural history of benign **breast** disease and **breast** cancer using **nipple** aspirate fluid" Cancer Epidemiology, Biomarkers and Prevention (Jan/Feb 1993) 2:3-10; Petrakis, "**Nipple** Aspirate Fluid in epidemiological studies of **breast** disease", Epidemiologic Reviews (1993) 15:188-195. More recently, markers have also been detected in **nipple** fluid. See Sauter et al, "**Nipple** aspirate fluid: a promising non-invasive method to identify cellular markers of **breast** cancer risk", British Journal of Cancer 76(4): 494-501 (1997). The detection of CEA in fluids obtained by a **nipple** blot is described in Imayama et al. (1996) Cancer 78: 1229-1234. Further, an **intraductal** aspiration method for cytodiagnosis in situations of spontaneous **nipple** discharge (Hou et al, Acta Cytologica 2000 v. 44:1029-1034) describes use of **intraductal** aspiration to collect specimens from spontaneously discharging ducts in order to make a cytodiagnosis.

SUMM [0003] **Breast** cancer is believed to originate in the lining of a single **breast** milk duct; and additionally the human **breast** is believed to contain from 6 to 9 of these ducts. See Sartorius, JAMA 224 (6): 823-827 (1973). Sartorius describes use of hair-like single lumen catheters that are inserted into **breast** ducts using an operating microscope and the ducts were flushed with saline solution as described in Cassels, D Mar. 20, 1973, The Medical Post, article entitled "New tests may speed **breast** cancer detection". After the fluid was infused, the catheter was removed because it was too small to collect the fluid, the **breast** was squeezed and fluid that oozed onto the **nipple** surface was removed from the surface by a capillary tube. Similarly, Love and Barsky, "**Breast**-duct endoscopy to study stages of cancerous **breast** disease", Lancet 348(9033): 997-999, 1996 describes cannulating **breast** ducts with a single lumen catheter and infusing a small amount of saline, removing the catheter and squeezing to collect the fluid that returns on the **nipple** surface. The use of a rigid 1.2 mm ductoscope to identify **intraductal** papillomas in women with **nipple** discharge is described in Makita et al (1991) **Breast** Cancer Res Treat 18: 179-188. It would be advantageous to collect the ductal fluid from within the duct and so. . .

SUMM . . . It is an object of the invention to provide a method for preparing a sample for use in diagnosis of **breast** cancer or pre-cancer.

SUMM [0005] It is another object of the invention to provide an isolated ductal fluid sample suitable for analyzing **breast** cancer and pre-cancer.

SUMM [0006] It is yet another object of the invention to provide a method for analyzing **breast** markers or epithelial cells.

SUMM . . . . emobidments described below. In one embodiment a method is provided for preparing a sample for use in the diagnosis of **breast** cancer or pre-cancer. A ductal fluid sample is isolated from one duct of a **breast** of a patient. The isolated ductal fluid is not mixed with ductal fluid from any other duct of the **breast**.

SUMM . . . According to another emobidment of the invention an isolated ductal fluid sample is provided. The sample is collected from a **breast** duct in a **breast**. The isolated ductal fluid is

not mixed with ductal fluid from any other **breast** duct.

SUMM [0009] According to still another embodiment of the invention a method is provided for analyzing **breast** markers or epithelial cells. The presence or absence of a marker in an isolated ductal fluid sample is determined. The sample is collected from a **breast** duct in a **breast**. The isolated ductal fluid not mixed with ductal fluid from any other **breast** duct.

SUMM [0010] The present invention thus provides the art with improved samples and sampling techniques for diagnosing and prognosing **breast** cancer and pre-cancer.

SUMM [0012] The invention comprises an isolated ductal fluid sample collected from a **breast** duct in a **breast**, the fluid not mixed with ductal fluid from any other **breast** duct. The isolated ductal fluid sample can be a sample from a non-discharging **breast** duct. A non-discharging duct is a **breast** duct that is not spontaneously discharging fluid or material, i.e., a duct which is not leaking fluid to the **nipple** surface. Spontaneously discharging ducts discharge fluid of various coloration. The spontaneous discharge itself is a warning sign usually requiring further investigation, such as, mammography, ductoscopy, and/or **galactography**. The present invention provides an isolated ductal fluid sample from a non-discharging duct, i.e., a ductal fluid and/or material sample, a portion of which would not otherwise have contacted the **nipple** surface. However, the isolated ductal fluid sample may also be from a discharging duct, provided the sample collected is not. . .

SUMM . . . particular marker. The markers can comprise those detailed herein and related markers that indicate the status or condition of the **breast**. The marker status can be used to identify pre-cancer or cancer of the **breast**. The ductal fluid sample is collected from one duct of a **breast** of a patient. Ductal fluids may be collected from multiple ducts of a **breast** or from ducts in both breasts of a patient, e.g., in sequence, provided the fluid and material from each duct. . . The ductal fluid sample when collected or provided is not mixed with ductal fluid from any other duct of the **breast**.

SUMM . . . status of the cells themselves. The invention provides the a ductal fluid sample comprising sufficient ductal epithelial cells from a **breast** duct for an analysis of the **breast** in which the duct is located. Insufficient ductal epithelial cells in a sample means that a cytological analysis of those. . . the accuracy of the cytological analysis is compromised. The method of the invention and the composition provide samples from single **breast** ducts that can be analyzed because the samples so isolated contain sufficient material for an adequate analysis to be made.. . . fluid in addition to cells, i.e., molecules present in the cells collected and/or in the extracellular material retrieved from the **breast** duct. An advantage provided by the invention is that many more cells than have been previously collected are collectable and. . .

SUMM [0015] Relatively undisrupted cells and clumps can be analyzed to provide information on the cellular status in the **breast** duct from which the sample was collected. Further, collection of the ductal fluid from the **breast** duct provides enough cells and/or other material from the duct to provide a useful analysis of the condition of

the **breast**. This is largely due to the fact that collection of the ductal fluid, cells and other material by infusing saline. . . can follow in order to prevent collapse of the ductal walls and provide the opportunity for a second or subsequent **intraductal** aspiration and/or retrieval. Squeezing and massaging the **breast** may also be used in concert with infusion and collection procedures. The

amount of material that is sufficient for analysis. . . clump having from at least 4 to 6 ductal epithelial cells. For example, the sample from a non-discharging or discharging **breast** duct may have at least from 10 to 20 ductal epithelial cells, 20 to 50, 50 to 100, 100 to. . .

SUMM [0016] The method of the invention is preparing a sample for use in diagnosis of **breast** cancer or pre-cancer comprising isolating a ductal fluid sample from one duct of a **breast** of a patient. The isolated ductal fluid is not mixed with ductal fluid from any other duct of the **breast**. The method can further include examining the isolated ductal fluid sample to determine the presence or absence of

a marker.. . . is not spontaneously discharging fluid. The marker for

analysis can be selected from any known and useful markers for a **breast** condition, including pre-cancer and/or cancer markers, and further optionally including markers listed herein.

SUMM . . . fluid in a predetermined quantity in the population, and standards are set for benchmarks indicating a particular condition in the **breast** (ie., pre-cancer or cancer, or their various subcategories). Examination of the ductal fluid can comprise examining the ductal fluid for. . .

SUMM . . . ductal fluid for the absence of a tumor suppressor molecule normally present in a given range or quantity in normal **breast** duct fluid or **breast** tissue. As an example, the ductal fluid can be examined for markers comprising such parameters as DNA content of

the. . .

SUMM . . . not being able to identify the specific duct to which abnormal cells or other findings can be attributed. Since most **breast** cancers begin in a single, isolated, milk duct of a **breast**, the identification of a specific duct as abnormal (i.e., cancerous or pre-cancerous) is extremely useful, especially in concert with sufficient. . . by a number of techniques that can be used together or separately and which are not limited to squeezing the **breast** , massaging the **breast**, applying negative pressure on the lumen to pull-up fluid into the lumen and/or collection receptacle, and using an additive in. . .

SUMM . . . The duct can be flushed by infusing saline into the duct until resistance is met, applying pressure and/or squeezing the **breast** , e.g., particularly at the base of the **breast**, and capturing the fluid that moves up through the duct after the pressure is applied. Flushing can continue by infusing. . .

SUMM [0022] In order to retrieve cells and ductal material sufficient for analysis of a single non-discharging **breast** duct and a corresponding diagnosis, a non-discharging duct can be accessed by a tool capable of infusing wash fluid and. . . infused and wash fluid mixed with ductal fluid (comprising cells and cellular material, etc.) is collected. The fluid from the **breast** duct can contain ductal epithelial cells, including cells of a stage considered to be pre-cancerous or cancerous as described, and. . .

SUMM [0023] The method is practiced by providing a ductal fluid sample from

at least one duct of a **breast** of the patient. Providing the ductal fluid sample can be accomplished by obtaining the sample from the **breast** or by receiving a sample that had been previously obtained. For example, a laboratory can receive a ductal fluid sample. . . a single duct. In general, collection of isolated ductal fluid not mixed with ductal fluid from another duct of the **breast** can be accomplished by accessing the duct with a **breast** duct access tool that infuses fluid and collects ductal fluid mixed with the infused fluid, while the tool remains in. . .

SUMM [0055] 30. at least a portion of **breast** cancer associated gene (BRCA), e.g., as described in Seances et al, Soc. Biol Fil 1998 v. 192:35-40, and Deng and. . .

SUMM . . . or suggested herein. Fluid collected from the milk ducts, can include constituents of biological fluids, e.g., those typically found in **breast** duct fluid, e.g., water, cells, cellular markers, molecular markers, nucleic acids, proteins, cellular debris, salts, particles or organic molecules. These. . .

SUMM [0066] Once the ductal fluid sample is retrieved from the **breast** it is examined for the presence of a marker such as, for example a protein, a polypeptide, a peptide, a. . .

SUMM . . . or for any marker providing evidence of neoplasia. The ductal epithelial cell can be derived from any part of the **breast** milk duct, including, e.g., the ductal lumen and/or the terminal ductal lobular unit (TDLU). Cells derived from the TDLU may. . .

SUMM . . . the wash fluid has been infused in the duct and the wash fluid and ductal fluid is collected from a **breast** duct, the cellular material can be separated and can be examined. The cellular material can include, e.g., substances selected from. . . used to examine whole cells. Other markers present in the cellular material, ductal fluid, or other material obtained from the **breast** duct can be analyzed as is appropriate for the marker being sought, including e.g., binding assays, immunohistochemistry, or using other. . .

SUMM . . . KAI1/CD82, a portion of KAI1/CD82, a nucleic acid encoding at least a portion of KAI1/CD82, at least a portion of **breast** cancer associated gene, TMS-1, a portion of TMS-1, a nucleic acid encoding a polypeptide comprising at least a portion of TMS-1; at least a portion of **breast** cancer associated gene (BRCA); absorption of a marker (e.g., iodide). fibroblast growth factor (FGF) protein, a portion of an FGF. . .

SUMM . . . may be used as a marker where a reduction in the marker identifies a cancerous or pre-cancerous condition in the **breast** .

SUMM . . . to identify cancer or pre-cancer as described in Mark et al (1999) Cancer Genet Cytogenet 108:26-31; Lundlin and Mertens (1998) **Breast** Cancer Res Treat 51:1-15; Newsham (1998) Am J Pathol 153:5-9; Larson etal (1998) Am J Pathol 152:1591-8; Adelaide et al. .

SUMM . . . used to examine whole cells. Markers present in the cellular material, ductal fluid generally, or other material obtained from the **breast** duct can be analyzed as is appropriate for the marker being sought, including, e.g., binding assays, immunohistochemistry, or using other. . .

SUMM . . . epithelial cells and other cells. Cytological assays that can be performed on the cells retrieved from a duct or from **nipple** aspirate can include e.g., assays described in King et al, J. Nat'l

Cancer Inst (1983) 71:1115-21, Wrensch etal. (1992) Am.. . . 130-141, Papanicolaou et al, (1958) Cancer, 11:377-409 and Goodson WH & King EB, Chapter 4: Discharges and Secretions of the **Nipple**, THE **BREAST**: COMPREHENSIVE MANAGEMENT OF BENIGN AND MALIGNANT DISEASES (1998) 2.sup.nd Ed. vol 2, Bland & Kirby eds. W.B. Saunders Co, Philadelphia,. . . regard to carcinoma in situ, Papanicolaou et al described cellular abnormalities, e.g., nuclear abnormalities diagnosed by cytology of fluid from **nipple** secretions containing ductal cells. The cytological examination of abnormal cells can also be conducted as described in Sartorius et al. . . fluid can be analyzed by cytological techniques by placing some of the fluid on a slide with a standard cytological **stain** and observing under a light microscope. The cells can be studied for atypical growth patterns in individual cells and clusters of cells using published methods, including Mouriquand J, (1993) S Karger Pub, "Diagnosis of Non-Palpable **Breast** Lesions: Ultrasonographically Controlled Fine-Needle Aspiration: Diagnostic and Prognostic Implications of Cytology" (ISBN 3805557477); Kline TS and IK, Pub Igaku-Shoin Medical ""**Breast** : Guides to Clinical Aspiration Biopsy" (LSBN 0896401596; Masood, American Society of Clinical Pathology: November 199S, "Cytopathology of the **Breast**" ISBN 0891893806; and Feldman PS, American Society of Clinical Pathology, November 1984, "Fine Needle Aspiration Cytology and Its Clinical Applications: **Breast** and Lung" ISBN 0891891846.

SUMM . . . ductal fluid include Silverman et al, (Can FNA biopsy separate atypical hyperplasia, carcinoma in situ, and invasive carcinoma of the **breast**? Cytomorphologic criteria and limitations in diagnosis, Diagnostic Cytopathology) 9(6): 713-28, 1993; Masood et al, (Immunohistochemical differentiation of atypical hyperplasia vs. carcinoma in situ of the **breast**) Cancer Detection & Prevention. 16(4): 225-35, 1992; Masood et al, (Cytologic differentiation between proliferative and nonproliferative **breast** disease in mammographically guided fine-needle aspirates) Diagnostic Cytopathology. 7 (6): 581-90, 1991; Masood S., (Occult **breast** lesions and aspiration biopsy: a new challenge) Diagnostic Cytopathology. 9(6): 613-4, 1993; Masood S., (Prognostic factors in **breast** cancer: use of cytologic preparations) Diagnostic Cytopathology. 13(5): 388-95, 1995, Novak and Masood, (Nuclear grooves in fine-needle aspiration biopsies of **breast** lesions: do they have any significance?) Diagnostic Cytopathology. 18(5): 333-7, 1998; Sidawy et al, (Interobserver variability in the classification of proliferative **breast** lesions by fine-needle aspiration: results of the Papanicolaou Society of Cytopathology Study) Diagnostic Cytopathology. 18(2): 15065, 1998; Masood et al,. . . Diagnostic Cytopathology. 18(1): 47-55, 1998; and Frykberg and Masood Copeland EM 3d. Bland KI., (Ductal carcinoma in situ of the **breast**) Surgery, Gynecology & Obstetrics 177(4): 425-40, 1993.

SUMM [0078] The invention also provides systems for preparing a sample for use in diagnosis of **breast** cancer or pre-cancer, the system comprising a tool to retrieve ductal fluid from a **breast** duct and instructions for use to isolate a ductal fluid sample from a duct, particularly a non-spontaneously discharging **breast** duct in order to determine the presence of one or more markers. Materials and instructions may also be included in. . . with the infused wash fluid

is one type of marker which can be used for diagnosing a condition in a **breast** duct. Instructions in the kit or system can include guidance for interpreting cytological data and/or other marker data in order. . . the system or kit. The instructions in the systems or kits can include directions according to the methods of identifying **breast** cancer or pre-cancer described herein, and possibly including any marker or markers or marker classification group or groups that could. . .

DETD [0080] A patient is prepared for a ductal access procedure. Using a ductal access tool, a duct on each **breast** is infused with sufficient wash fluid, and the wash fluid mixed with ductal fluid is collected separately from each accessed. . . KAI1/CD82, a portion of KAI1/CD82, a nucleic acid encoding at least a portion of KAI1/CD82, at least a portion of **breast** cancer associated gene, TMS-1, a portion of TMS-1, a nucleic acid encoding a polypeptide comprising at least a portion of TMS-1; at least a portion of **breast** cancer associated gene (BRCA); absorption of a marker (e.g., iodide). fibroblast growth factor (FGF) protein, a portion of an FGF. . .

CLM What is claimed is:

1. A method for preparing a sample for use in diagnosis of **breast** cancer or pre-cancer comprising: isolating a ductal fluid sample from one duct of a **breast** of a patient, said isolated ductal fluid not mixed with ductal fluid from any other duct of the **breast**.

. . . of maspin, a nucleic acid encoding a polypeptide comprising at least a portion of maspin, at least a portion of **breast** cancer associated (BRCA) gene, and at least a portion of a BRCA gene product; CDw60 protein, a portion of CDw60. . .

13. An isolated ductal fluid sample collected from a **breast** duct in a **breast**, said isolated ductal fluid not mixed with ductal fluid from any other **breast** duct.

. . . isolated ductal fluid sample as in claim 13, a portion of said isolated ductal fluid not spontaneously discharging from the **breast** duct.

20. A method for analyzing **breast** markers or epithelial cells, comprising: determining the presence or absence of a marker in an isolated ductal fluid sample collected from a **breast** duct in a **breast**, said isolated ductal fluid not mixed with ductal fluid from any other **breast** duct.

. . . of maspin, a nucleic acid encoding a polypeptide comprising at least a portion of maspin, at least a portion of **breast** cancer associated (BRCA) gene, and at least a portion of a BRCA gene product; CDw60 protein, aportion of CDw60 protein. . .

L18 ANSWER 9 OF 13 USPATFULL

AB Methods, kits, and apparatus for locating, labelling, and accessing **breast** ducts are described. An orifice to one or more ductal networks is labelled using a specific binding substance, typically an. . . . orifices permits reliable identification and access to each of the multiple ductal networks which may be present in an individual **breast**.

SUMM **Breast** cancer is the most common cancer in women, with well over 100,000 new cases being diagnosed each year. Even greater numbers of women, however, have symptoms associated with **breast** diseases, both benign and malignant, and must undergo further diagnosis and evaluation in order to determine whether **breast** cancer exists. To that end, a variety of diagnostic techniques have been developed, the most common of which are surgical. . .

SUMM . . . of other diagnostic techniques have been proposed for research purposes. Of particular interest to the present invention, fluids from the **breast** ducts have been externally collected, analyzed, and correlated to some extent with the risk of **breast** cancer. Such fluid collection, however, is generally taken from the surface of the **nipple** and represents the entire ductal structure. Information on the condition of an individual duct is generally not provided. Information on individual ducts can be obtained through cannulation and endoscopic examination, but such examinations have been primarily in women with **nipple** discharge or for research purposes and have generally not examined each individual duct in the **breast**.

SUMM Since **breast** cancer usually arises form a single ductal system and exists in a precancerous state for a number of years, endoscopy in and fluid collection from individual **breast** ducts holds great diagnostic promise for the identification of intermediate markers. Much of the promise, however, cannot be realized until access to each and every duct in a patient's **breast** can be assured. Presently, ductal access may be obtained by a magnification of the **nipple** and identification of ductal orifice(s) using conventional medical magnifiers, such as magnification loupes. While such magnified examination is relatively simple,. . . the ductal orifices can be confused with other tissue structures, such as sebaceous glands and simple keratin-filled caruncles of the **nipple**. Thus, before ductal techniques can be further developed for diagnostic, research, or other purposes, it will be useful to provide. . . ductal orifices to distinguish them from other orifices, and allow subsequent ductal access in selected and/or all ducts in each **breast**.

SUMM Publications by the inventors herein relating to **breast** duct access include Love and Barsky (1996) Lancet 348: 997-999; Love (1992) "**Breast** duct endoscopy: a pilot study of a potential technique for evaluating **intraductal** disease," presented at 15th Annual San Antonio **Breast** Cancer Symposium, San Antonio, Tex., Abstract 197; Barsky and Love (1996) "Pathological analysis of **breast** duct endoscoped mastectomies," Laboratory Investigation, Modern Pathology, Abstract 67. A description of the inventors' **breast** duct access work was presented in Lewis (1997) Biophotonics International, pages 27-28, May/June 1997.

SUMM **Nipple** aspiration and/or the introduction of contrast medium into **breast** ducts prior to imaging are described in Sartorius (1995) **Breast** Cancer Res. Treat. 35: 255-266; Satorious et al. (1977) "Contrast ductography for the recognition and localization of benign and malignant **breast** lesions: An improved technique," in: Logan (ed.), **Breast** Carcinoma, New York, Wiley, pp. 281-300; Petrakis (1993) Cancer Epidem. Biomarker Prev. 2: 3-10; Petrakis (1993) Epidem. Rev. 15: 188-195; Petrakis (1986) **Breast** Cancer Res. Treat. 8: 7-19; Wrensch et al. (1992) Am. J. Epidem. 135: 130-141; Wrensch et al. (1990) **Breast** Cancer Res. Treat. 15: 39-51; and Wrensch et al. (1989) Cancer Res. 49: 2168-2174. The presence of abnormal biomarkers in fine needle **breast** aspirates is

described in Fabian et al. (1993) Proc. Ann. Meet. Am. Assoc. Cancer Res. 34: A1556. The use of a rigid 1.2 mm ductoscope to identify **intraductal** papillomas in women with **nipple** discharge is described in Makita et al. (1991) **Breast** Cancer Res. Treat. 18: 179-188. The use of a 0.4 mm flexible scope to investigate **nipple** discharge is described in Okazaki et al. (1991) Jpn. J. Clin. Oncol. 21: 188-193. The detection of CEA in fluids obtained by a **nipple** blot is described in Imayama et al. (1996) Cancer 78: 1229-1234. Delivery of epithelium-destroying agents to breasts by ductal cannulation. . .

SUMM The present invention provides improved methods, kits, and other apparatus for locating **breast** ducts in the breasts of human female patients. In particular, the methods of the present invention permit reliable identification of the orifices within the **nipple** of a **breast** which lead to each of the multiple ductal networks within the **breast**. By reliably identifying each orifice, all of the ductal networks can be located and subsequently accessed for diagnostic, risk assessment,. . .

SUMM In a first aspect of the present invention, a method for locating an orifice of a **breast** duct comprises labelling ductal cells disposed at the ductal orifice with a visible or otherwise detectable label. The orifice may. . . a catheter or fiberoptic viewing scope, can be introduced through at least one of the orifices and into the associated **breast** duct. The method may further comprise introducing the same or a different access device through other orifices, often into each of the orifices to permit diagnosis, treatment, or other evaluation of all of the ductal networks of a **breast**.

SUMM In a second aspect, the present invention comprises a method for labelling the orifice of a **breast** duct. The method includes treating a **nipple** to expose tissue in an orifice of each duct. The treated **nipple** is then exposed to a labelling reagent capable of specifically binding to a tissue marker characteristic of tissue at the. . . label at the orifice, permitting subsequent location of the orifice as described above. The treating step preferably comprises washing the **nipple** with a keratinolytic agent, such as 5% to 50% acetic acid (by weight), to remove keratin-containing materials which normally occlude. . . been found by the inventors herein that the ductal epithelium extends to within 0.1 mm to 0.2 mm of the **nipple** orifice and is sufficiently exposed to the surface of the **nipple** to permit labelling according to the methods of the present invention. Exemplary markers include cytokeratins, such as cytokeratin 8, cytokeratin. . . specific for the marker. The antibody may be directly labelled with a visible label, such as a fluorescent label, a **dye** label, a chemiluminescent label, or the like. Alternatively, the labeling reagent may comprise two or more components, typically including a. . .

SUMM In a fourth aspect of the present invention, a kit for labelling **breast** duct orifices comprises a labelling reagent or reagents capable of specifically labelling a cellular marker at the ductal orifice, instructions. . .

SUMM In a fifth aspect of the present invention, a kit for accessing a **breast** duct comprises a labelling reagent capable of specifically labelling a ductal orifice and optionally a keratinolytic agent for treating the **nipple** prior to exposure of the

labelling reagent. The kit further comprises an access device capable of being inserted through a. . .

DRWD FIG. 1 is an anterior view of a human female **breast**, shown in section, and illustrating three of the six to nine ductal networks extending inwardly from the **nipple**.

DRWD FIG. 2 is an enlarged view of the **nipple** of FIG. 1 illustrating the orifices leading to each of the three ductal networks.

DRWD FIG. 4 is a schematic illustration of the appearance of a **nipple** which has been labelled with visible markers according to the methods of the present invention.

DETD The present invention comprises methods for locating, labelling, and accessing the ductal networks in human female breasts. A typical **breast** B is illustrated in FIG. 1 and includes a **nipple** N and from six to nine ducts D.

DETD Three ductal networks D.sub.1-3 extending inwardly from the **nipple** N into the **breast** tissue are illustrated. As best seen in FIG. 2, each ductal network D.sub.1-3 begins with an orifice O.sub.1-3 which lies at the surface of the **nipple** N and extends inwardly through a ductal sinus S.sub.1-3 and then into a branching network. Each network D comprises a. . . of successively smaller lumens which are arranged in complex, three-dimensional patterns. The networks of each duct will overlap within the **breast** tissue but will not be interconnected. The present invention relies on identifying and labelling tissue in the orifice O of each duct D within the **nipple** N. Usually, there will be from six to nine orifices which open into a like number of ductal networks. An. . . ductal epithelium to the squamous epithelium of the skin is found within about 0.1 mm to 0.2 mm of the **nipple** surface. Typically, the ductal orifice will be occluded with a conical keratin plug measuring about 0.5 mm to 1 mm. . .

DETD . . . that the label will be introduced in a manner such that it will bind to the orifice region within the **nipple** but not bind (or will bind to a significantly lesser extent, usually at least 10-fold less) to other regions of the **nipple**. In this way, binding of the label to the orifice will be a discernable indication that the orifice is present. . .

DETD . . . the present invention, the tissue marker(s) will be an antigenic or epitopic site characteristic of the epithelial lining of the **breast** duct. Surprisingly, it has been found that the epithelial lining extends sufficiently far into the orifice region of the duct. . . and by molecules present in the membrane lining, such as E cadherin, epithelial membrane antigen (EMA), and the like. Suitable **breast** epithelial tissue markers are described, for example, in Moll et al. (1982) Cell 30:11-19; Gown and Vogel (1984) Am. J.. . .

DETD . . . label those markers M which are near the orifice O. Frequently, it will be desirable or necessary to wash the **nipple** with a solution capable of unblocking the orifice to permit binding of the antibodies or other labelling reagent. For example,. . .

DETD In an exemplary protocol according to the present invention, the **nipple** is first dekeratinized with 5% to 50% acetic acid to remove keratin and other potentially blocking and contaminating substances from. . . cytokeratin or other epithelial cytoplasmic or surface membrane marker, such as the antibodies described above, is then

applied to the **nipple** surface. The antibody is preferably linked to a fluorescent marker, more preferably fluorescein, and the fluorescein-labelled antibody delivered in a. . . be run. For example, labelled antibodies of the same Ig class as the specific antibody may be exposed to the **nipple** at the same dilution. By comparing the results with the specific antibody and the control antibody, non-specific binding can be. . .

DETD A. Dekeratinizing the **Nipple**

DETD Acetic acid is mixed with Velvacrol (50% v/w), a pharmaceutical vehicle comprising an aqueous mixture of petrolatum/mineral oil, acetyl **alcohol**, sodium laural sulfate, cholesterol, methylparaben, butylparaben, and propylparaben. To keep the acetic acid in solution, methyl cellulose (100 mg) is pre-added to the Velvacrol (5 g). The mixture possesses a uniform pasty consistency and is applied to the **nipple** as an ointment or past. The keratinolytic agent is typically left on the **nipple** for twenty-four hours or longer to remove the keratin plugs from the ductal orifices.

DETD . . . not necessary. A mouse monoclonal primary antibody is used as a

dilution of 1:5 to 1:100 and maintained on the **nipple** for one hour at room temperature. After such incubation, the **nipple** is washed with phosphate buffered saline PBS and a secondary antibody (fluoresceinated goat anti-mouse antibody) used at a dilution of from 1:5 to 1:1000 fold at room temperature. After washing with PBS, the **nipple** may be examined under ultraviolet (UV) light at a wavelength selected for the particular fluorochrome being used. A control can. . . similar class, but without specificity for any of the ductal epithelial or other markers which may be present on the **nipple**. This method will provide successful labelling of the ductal orifices and permit subsequent cannulation and examination of each orifice.

DETD . . . performed under white (visual) light. One or more ducts are cannulated first with a rigid metal duct-probe (6 Fr Taber-Rothschild **Galactography** Kit, Manan Medical Products Inc., Northbrook, Ill.) dilated to 0.45 mm to 0.5 mm. A guide wire (0.4 mm) is. . .

DETD . . . ml air. At the end of the final insufflation, the orifice is held shut by pinching the end of the **nipple**. An endoscope (FVS-3000, M&M Company, Tokyo), which is 0.4 mm in outer diameter is then threaded into the duct orifice. . .

CLM What is claimed is:

1. A method for locating an orifice of a **breast** duct, said method comprising: labeling cellular material at the orifice with a detectable label coupled to an antibody specific for. . .

2. A method as in claim 1, wherein labeling comprises: treating a **nipple** to expose tissue at the ductal orifice; and exposing the treated **nipple** to labeled the antibody, wherein the antibody specifically binds to a membrane or cytoplasmic tissue marker characteristic of the tissue. . . orifice, and wherein the antibody specifically binds to the tissue at the orifice but not to other tissue on the **nipple**.

3. A method as in claim 2, wherein treating comprises washing the **nipple** with a keratinolytic agent.

. . . method as in claim 1, wherein the detectable label is selected from the group consisting of a fluorescent label, a **dye** label and chemiluminescent label.

. . . in claim 6, wherein the detectable label is a fluorescent label and

the ductal orifice is located by exposing the **nipple** to excitation radiation and observing fluorescence at the ductal orifice.

11. A method for labeling a **breast** duct, said method comprising: treating a **nipple** to expose tissue at the ductal orifice; and exposing the treated **nipple** to a detectable label coupled to an antibody specific for a tissue marker characteristic of the tissue at the ductal orifice, wherein the antibody specifically binds to the tissue at the orifice but not to other tissue on the **nipple**.

12. A method as in claim 11, wherein treating comprises washing the **nipple** with a keratinolytic agent.

. . . method as in claim 11, wherein the detectable label is selected from the group consisting of a fluorescent label, a **dye** label and a chemiluminescent label.

19. A method for accessing a **breast** duct, said method comprising: labeling cellular material at a ductal orifice with a detectable label coupled to an antibody specific. . .
20. A method as in claim 19, wherein the labeling comprises: cleaning a **nipple** to expose tissue at the ductal orifice; and exposing the cleaned **nipple** to the labeled antibody, wherein the antibody specifically binds to a tissue marker characteristic of the tissue at the ductal. . . orifice, and wherein the antibody specifically binds to the tissue at the orifice but not to other tissue on the **nipple**.

21. A method as in claim 20, wherein the cleaning comprises washing the **nipple** with a keratinolytic agent.

. . . method as in claim 19, wherein the detectable label is selected from the group consisting of a fluorescent label, a **dye** label and a chemiluminescent label.

L18 ANSWER 10 OF 13 CANCERLIT DUPLICATE 1
TI Preoperative methylene blue staining of galactographically suspicious **breast** lesions.
AB Microdochectomy is the standard treatment of galactographically suspicious **breast** lesions. Precise preoperative marking of the suspicious duct and **intraductal** lesions facilitates selective minimal-volume microdochectomy. Methylene blue **dye** staining fulfills this criterion. A retrospective review of our experience of preoperative methylene blue staining in 30 patients with unilateral spontaneous nonlactiferous single duct **nipple** discharge operated on during 1986-1995 in the Oulu University Hospital for galactographically suspicious **breast** lesions. **Galactography** was successful in 29 out of 30 (93.3%) cases. Preoperative methylene blue staining was attempted in all cases on the. . . selective minimal-volume microdochectomy easy to perform. The failure of methylene blue staining led to quadrantectomy in 4 cases and smaller **breast** resections in the remaining 4 cases. Preoperative methylene blue **dye** staining crucially facilitates selective minimal-volume microdochectomy. An interval between primary **galactography** and later methylene blue staining leads to failures in approximately one

quarter of the cases. A higher success rate would necessitate scheduling the microdochectomy on the same day as the primary **galactography** (and the subsequent methylene blue staining in suspicious cases).

CT Check Tags: Female; Human
Adult
Aged
*__Breast__ Neoplasms: RA, radiography
__Breast__ Neoplasms: SU, surgery
*Dyes: DU, diagnostic use
*Methylene Blue: DU, diagnostic use
Middle Age
Papilloma, __Intraductal__: RA, radiography
Papilloma, __Intraductal__: SU, surgery
Preoperative Care
Retrospective Studies

L18 ANSWER 11 OF 13 CANCERLIT DUPLICATE 2

TI Ductography is a useful technique in evaluation of abnormal **nipple** discharge.

AB The purpose of this study was to evaluate the utility of ductography, or **galactography**, in identifying ductal abnormalities in patients presenting with abnormal **nipple** discharge and to correlate these findings with pathologic results. Abnormal **nipple** discharge was defined as either bloody or testing positive for occult blood. Milky discharge (galactorrhea) was not evaluated. From July 1992 to June 1994, a total of 43 women presented to the UCLA **Breast** Center with complaints of abnormal **nipple** discharge. Mean age of the patients was 54.9 years. All patients underwent technically adequate ductography. A total of 25 patients. . . histologic findings. We conclude that ductography is an effective and safe means of identifying ductal abnormalities in patients with abnormal **breast** discharge. A high incidence of benign **intraductal** papilloma and a moderate risk of cancer and precancerous lesions were identified. We believe that patients with abnormal **nipple** discharge should undergo routine ductography and **dye** localization before surgery.

CT Check Tags: Female; Human
__Breast__ Diseases: RA, radiography
__Breast__ Neoplasms: RA, radiography
Dilatation, Pathologic
Evaluation Studies
Middle Age
*Nipples: RA, radiography
Papilloma, __Intraductal__: RA, radiography

L18 ANSWER 12 OF 13 EMBASE COPYRIGHT 2002 ELSEVIER SCI. B.V.

AB Selective galactophorectomy implies excision of one or more galactophorous ducts when **intraductal** tumors are suspected or detected. In patients with **nipple** discharge, galactophorectomy becomes an elective procedure when cellular atypies are detected and are the only sign of tumoral or pre-tumoral disease, when **galactography** reveals **intraductal** lesions and, as a diagnostic mean, when cytology is suggestive of disease but clinical findings, mammography and **galactography** are negative. On the basis of more than 350 selective galactophorectomies performed, the author: 1) describes in detail how to. . . highly selective 2) suggests the areolar Z incision as opposed to the traditional radial or periareolar incisions thus avoiding possible **nipple** retraction and making excision most

selective 3) advises that excision should always include enough surrounding tissue without **dye** to be sure that the affected area is removed 4) stresses both curative and diagnostic effectiveness of the procedure in. . .

CT Medical Descriptors:
***breast surgery**
***breast tumor: DI, diagnosis**
***breast tumor: SU, surgery**
adult
article
breast discharge
breast papilloma: SU, surgery
breast papilloma: DI, diagnosis
carcinoma in situ: DI, diagnosis
carcinoma in situ: SU, surgery
cytology
female
galactography
histopathology
human
incision
intraductal carcinoma: DI, diagnosis
intraductal carcinoma: SU, surgery
invasive carcinoma: DI, diagnosis
invasive carcinoma: SU, surgery
major clinical study
mammography
surgical technique

L18 ANSWER 13 OF 13 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.DUPLICATE 3

TI **GALACTOGRAPHY** THE DIAGNOSTIC PROCEDURE OF CHOICE FOR **NIPPLE** DISCHARGE.

AB **Galactography** was performed in 204 women with a **nipple** discharge and the secretion confirmed histopathologically. All 116 **intraductal** tumors (papilloma, papillomatosis, carcinoma), which were associated with a serous or bloody discharge, were detected preoperatively. A palpable mass had. . . the patients with carcinoma. All patients with a spontaneous bloody or serous discharge from a single lactiferous orifice should undergo **galactography** in addition to physical, cytological, and mammographic examination. **Intraductal** injection of methylene blue **dye** will demonstrate the affected duct system to the surgeon and can often make surgery less radical or even unnecessary.

IT Miscellaneous Descriptors
HUMAN TUMOR PAPILLOMA PAPILLOMATOSIS CARCINOMA SEROUS BLOODY DISCHARGE METHYLENE BLUE **DYE** INTRA DUCTAL INJECTION MAMMOGRAPHY HISTO PATHOLOGY SURGERY

=>

L18 ANSWER 13 OF 13 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.DUPLICATE 3

AN 1984:235832 BIOSIS

DN BA77:68816

TI **GALACTOGRAPHY** THE DIAGNOSTIC PROCEDURE OF CHOICE FOR **NIPPLE** DISCHARGE.

AU TABAR L; DEAN P B; PENTEK Z

CS MAMMOGRAPHY DEP., FALUN CENT. HOSP., 791 82 FALUN, SWEDEN.

SO RADIOLOGY, (1983) 149 (1), 31-38.
CODEN: RADLAX. ISSN: 0033-8419.

FS BA; OLD

LA English

AB **Galactography** was performed in 204 women with a **nipple** discharge and the secretion confirmed histopathologically. All 116 **intraductal** tumors (papilloma, papillomatosis, carcinoma), which were associated with a serous or bloody discharge, were detected preoperatively. A palpable mass had little diagnostic significance, and exfoliative cytology was positive in only 11% (2/18) of the patients with carcinoma. All patients with a spontaneous bloody or serous discharge from a single lactiferous orifice should undergo **galactography** in addition to physical, cytological, and mammographic examination. **Intraductal** injection of methylene blue **dye** will demonstrate the affected duct system to the surgeon and can often make surgery less radical or even unnecessary.

CC Microscopy Techniques - Histology and Histochemistry 01056
Cytology and Cytochemistry - Human *02508
Radiation - Radiation and Isotope Techniques 06504
Biochemical Studies - General 10060
Anatomy and Histology, General and Comparative - Surgery 11105
Anatomy and Histology, General and Comparative - Radiologic Anatomy *11106
Anatomy and Histology, General and Comparative - Microscopic and Ultramicroscopic Anatomy *11108
Pathology, General and Miscellaneous - Comparative *12503
Pathology, General and Miscellaneous - Diagnostic 12504
Pathology, General and Miscellaneous - Therapy 12512
Cardiovascular System - Blood Vessel Pathology *14508
Blood, Blood-Forming Organs and Body Fluids - Other Body Fluids 15010
Reproductive System - General; Methods *16501
Reproductive System - Pathology *16506
Neoplasms and Neoplastic Agents - Diagnostic Methods *24001
Neoplasms and Neoplastic Agents - Pathology; Clinical Aspects; Systemic Effects *24004
Neoplasms and Neoplastic Agents - Therapeutic Agents; Therapy *24008

BC Hominidae 86215

IT Miscellaneous Descriptors
HUMAN TUMOR PAPILLOMA PAPILLOMATOSIS CARCINOMA SEROUS BLOODY DISCHARGE METHYLENE BLUE **DYE** INTRA DUCTAL INJECTION MAMMOGRAPHY HISTO PATHOLOGY SURGERY

RN 61-73-4D (METHYLENE BLUE)

=>

L21 ANSWER 4 OF 7 USPATFULL

AB A disposable **breast pad**, which does not require the use of a brassiere for support, comprises a circular body having a surface profile adapted to conform to the contour of the female **breast**. A portion of the circular body is cut out and removed to form an opening in the circular body. An insert is provided to cover the opening and is attached to the circular body. The insert is made of mesh material and has elastic strands sewn therein. The insert will allow the **pad** to expand, if necessary, thereby ensuring a comfortable fit for breasts of different sizes and shapes. A pressure sensitive skin safe adhesive is used to secure the **pad** directly to the **breast**.

AN 2000:30651 USPATFULL

TI Disposable **breast pad**

IN Coburn, Shonda L., 1020 11th St., Marysville, CA, United States 95901

PI US 6036577 20000314

AI US 1998-25296 19980218 (9)

DT Utility

FS Granted

EXNAM Primary Examiner: Calvert, John J.; Assistant Examiner: Hoey, Alissa L.

LREP Litman, Richard C.

CLMN Number of Claims: 6

ECL Exemplary Claim: 1

DRWN 4 Drawing Figure(s); 3 Drawing Page(s)

LN.CNT 186

TI Disposable **breast pad**

TI Disposable **breast pad**

AB A disposable **breast pad**, which does not require the use of a brassiere for support, comprises a circular body having a surface profile adapted to conform to the contour of the female **breast**. A portion of the circular body is cut out and removed to form an opening in the circular body. An. . . circular body. The insert is made of mesh material and has elastic strands sewn therein. The insert will allow the **pad** to expand, if necessary, thereby ensuring a comfortable fit for breasts of different sizes and shapes. A pressure sensitive skin safe adhesive is used to secure the **pad** directly to the **breast**.

SUMM The present invention relates to absorbent materials worn in contact with the skin, and more specifically, to nursing or **breast** pads which may be comfortably secured and fitted to breasts of various sizes and shapes without the use of a. . .

SUMM Disposable nursing or **breast** pads are known in the art and are used by new mothers to prevent milk, which may leak from the breasts, from staining garments worn by the mother. Prior art **breast** pads require that a brassiere is worn to prevent the **pad** from slipping out of the proper position. While the use of a brassiere may be desirable for daytime wear, the brassiere may prove to be restrictive and uncomfortable when sleeping. Furthermore, movement during sleep may cause the **pad** to slip from a proper position thereby causing leaked milk to stain bedding and/or night clothes. Also, the **breast** pads of the prior art do not adequately adjust to breasts of different sizes and shapes.

SUMM U.S. Pat. Nos. 3,442,268 (Bird), 4,047,534 (Thomaschefsky et al.), 4,074,721 (Smits et al.), 4,125,114 (Repke), and French Patent 958,747

show **breast** pads designed to be inserted into a brassiere.

SUMM U.S. Pat. Nos. 4,700,699 (Tollerud et al.) and 5,603,653 (Hartman) show **breast** pads with adhesive on an outer surface so that the pads adhere to a brassiere.

SUMM U.S. Pat. No. 5,326,305 (Fochler) shows a **breast pad** attached to a garment.

SUMM U.S. Pat. No. 4,875,492 (Mitchell et al.) shows a **breast pad** which is molded to fit the **breast** and supported in a brassiere.

SUMM U.S. Pat. No. 4,333,471 (Nakai) shows a **breast nipple** cover with adhesive for direct attachment to the wearer's skin. The cover is also provided with cut out portions to. . .

SUMM . . . and patents, taken either singularly or in combination, is seen to describe the instant invention as claimed. Thus a disposable **breast pad** solving the aforementioned problems is desired.

SUMM The present invention describes a disposable **breast pad** which will prevent leakage of mother's milk. The **breast pad** is an enlarged circular body and is adapted to cover the **breast**'s **nipple**. The **breast pad** is constructed of highly absorbent material and has a skin safe adhesive applied around the circumference thereof. The adhesive allows the **pad** to be secured directly to the **breast** and to remain in place without the use of a brassiere. A sector shaped portion is cut out of the **pad** which allows the **pad** to adjust to breasts of different sizes and shapes while ensuring that the **pad** completely covers the **nipple**.

SUMM Accordingly, it is a principal object of the invention to provide an improved **breast pad** which is economical and is easy to use.

SUMM It is another object of the invention to provide an improved **breast pad** that is disposable and especially adapted for nighttime wear.

SUMM It is a further object of the invention to provide an improved **breast pad** that is comfortable and does not require the use of a brassiere.

SUMM Still another object of the invention is to provide an improved **breast pad** that is self adjusting to fit breasts of different sizes and shapes.

DRWD FIG. 1 is a front view of a disposable **breast pad** according to the present invention.

DRWD FIG. 2 is a rear view of a disposable **breast pad** according to the present invention with portions pulled away to show the adhesive bead.

DRWD FIG. 3 is a cross-sectional view of a **breast pad** according to the present invention taken to show the **pad**'s layer construction.

DRWD FIG. 4 is a perspective environmental view of a **breast pad** according to the present invention.

DETD The present invention is a disposable **breast** or nursing **pad** constructed as a circular body 10 which has a diametrical dimension of approximately 12 centimeters and wherein the circular body's surface, in profile, is adapted to conform with the contour of the female **breast** (FIG. 4).

DETD . . . 3, the body 10 is constructed of a plurality of coextensive layers. An inner layer 12, which would contact the **breast**, is moisture permeable and allows fluid to pass therethrough into an

absorbent layer 14. An outer layer 16 is impermeable. . .

DETD . . . 20 to the circumference of the circular body. The truncated apex of the cut out sector leaves a more rounded **pad** in the center of the circular body such that the **pad** will completely cover the wearer's **nipple**.

DETD . . . peripheral edge as illustrated in FIGS. 1 and 2. This construction prevents direct contact of the elastic strands with the **breast** and enhances wearer comfort. The mesh material 24 and elastic strands 26 are securely attached to the body 10 by. . .

DETD . . . applied around the circumference of the circular body on the inner layer thereof such that the adhesive would contact the **breast** when the **pad** is worn (FIG. 2). A bead width of approximately 8/10 of a centimeter has been found sufficient to hold the **pad** in place on the **breast**. The adhesive does not extend into the area covered by the insert 22. Any of numerous medical pressure sensitive adhesives used on bandages and approved by the U.S. Food and **Drug** Administration may be employed as an adhesive on the present invention.

DETD . . . circular body 10. The release liner 30 provides a protective barrier for the adhesive and ensures hygienic conditions for the **breast** contacting inner layer of the **pad**.

DETD . . . is used by first peeling the paper backing from the circular body 10. The body is then positioned on the **breast** so that the center of the **pad** covers the **nipple**. Gently pressing the **pad** on the **breast** will cause the insert 22 to expand ,if necessary, thereby ensuring a comfortable fit for any **breast** size or shape. The **pad** is then pressed down around the circumference thereof so that the pressure sensitive adhesive will secure the **pad** to the **breast** of the user. No brassiere is required to further secure the **pad**. To remove, the **pad** is simply peeled from the **breast** and properly discarded.

CLM What is claimed is:

1. A disposable **breast pad** comprising: a circular body, said circular body having a first layer adapted to contact a female **breast**, said first layer made of moisture permeable material; a second layer positioned on said first layer and coextensive therewith, said. . .

2. A disposable **breast pad** as defined in claim 1 wherein a release liner, coextensive with said circular body, is positioned to cover said first. . .

3. A disposable **breast pad** as defined in claim 1 wherein elastic strands are attached between said mesh inner layer and said mesh outer layer. . .

4. A disposable **breast pad** as defined in claim 1 wherein said opening, in plan view, approximates a configuration of a truncated sector having two. . .

5. A disposable **breast pad** as defined in claim 4 wherein said two sides form an angle of approximately 60 degrees therebetween.

6. A disposable **breast pad** as defined in claim 4 wherein said two sides are of equal lengths.

L21 ANSWER 5 OF 7 USPATFULL

AB A method and apparatus for collecting medical data from a test subject

while optionally preserving anonymity for the test subject. The method includes steps of collecting a sample from the test subject and taking biometric data from the test subject. The biometric data permit a high order of probability of correlation of the test subject with the sample and with test results derived from the sample. The method optionally further includes a step of providing the test subject with a unique correlating code also for permitting unique correlation of the test subject with the sample and with test results derived from the sample, and further desirably includes a step of labeling the sample with information including the biometric data.

AN 1999:27390 USPATFULL
TI Method, apparatus and system for verification of human medical data
IN Beecham, James E., 8820 Cortile Dr., Las Vegas, NV, United States 89134
PI US 5876926 19990302
AI US 1997-910062 19970806 (8)
RLI Continuation-in-part of Ser. No. US 1996-686211, filed on 23 Jul 1996
DT Utility
FS Granted
EXNAM Primary Examiner: Stucker, Jeffrey
LREP Seed & Berry LLP
CLMN Number of Claims: 17
ECL Exemplary Claim: 1
DRWN 16 Drawing Figure(s); 10 Drawing Page(s)
LN.CNT 1537
TI Method, apparatus and system for verification of human medical data
SUMM Various types of samples may be collected for various purposes, including blood typing, **drug** testing and testing for infectious or genetic diseases. Depending on the purpose of the testing, various specific biological specimens may. . .
SUMM . . . results leading to improper diagnosis and treatment of the patient or improper identification of one individual as having used some **drug** or substance.
SUMM . . . studies or where the test subject wishes to have anonymity as in HIV testing and in certain circumstances for urine **drug** testing associated with employment. In such circumstances, one known method for accomplishing the task of secure and specific identification of. . .
SUMM Where these types of records are **drug** testing results, they are usually collected by and for a single employer; a subsequent employer may well be denied access. . .
SUMM Hair and fingernails both include metabolites of substances ingested by the subject and either may be used to determine **drug** use in particular. Both types of samples are subject to contamination from external sources, e.g., walking through a room laden. . .
SUMM Once collected, biological samples are evaluated to determine a variety of characteristics. These include (A) **drug** testing, (B) testing for diseases such as infectious diseases and (C) testing to identify genetic predisposition for developing disease.
SUMM A. **Drug** testing.
SUMM **Drug** testing may be carried out on any of many types of samples collected from a test subject. Urine testing is. . . metabolites over a longer interval of the test subject's recent life. Hair samples, for example, may be tested to determine **drug** usage over a relatively long period of time, however, relatively little is known about the actual accuracy of such tests. Breath samples and oral mucosal transudate samples may provide useful or legally

significant information regarding recent **drug** use or about disease status of the individual.

SUMM . . . not provide the test subject with any verifiable way of providing the test results to a third party. Additionally, recent multiple-**drug** therapies can reduce presence of HIV and indicia of HIV to immeasurably low levels but these therapies introduce detectable levels. . .

SUMM . . . testing for genetic markers of disease and hereditary susceptibility to diseases or specific conditions is a rapidly developing area of **medicine**. Current methods include DNA and RNA analysis based on hybridization techniques such as fluorescence in situ hybridization, restriction length polymorphism. . .

SUMM . . . cell anemia, muscular dystrophy of various types, fragile X disease, chronic myelogenous leukemia, predisposition to development of cancer such as **breast** cancer gene BRCA-1 or colon cancer gene. These issues have had considerable public attention focused on them because they may. . .

SUMM A woman with BRCA1 has a lifetime risk of developing **breast** cancer of 85% versus 11% lifetime risk for a woman who does not have the BRCA1 gene. Surveillance by mammogram. . .

SUMM . . . provide a voluntary method, system and apparatus for identifying individuals who are free of HIV indicia and/or indicia of recreational **drug** usage without risk of compromising the individual's identity.

SUMM . . . a new system and method for anonymously testing for human HIV status and/or antigens or antibodies for human diseases and/or **drug** levels of therapeutic drugs known to be used in treatment of infectious diseases and/or **drug** levels of "recreational" drugs.

SUMM . . . for determining infectious status of the test subject and/or presence of antigens or antibodies for human diseases and/or presence of **drug** levels of therapeutic drugs known to be used in treatment of infectious diseases and/or presence of **drug** levels of "recreational" drugs and/or genetic testing, linking the result, the biometric data and the unique correlating code together to. . .

SUMM . . . for evidence of presence of human immunodeficiency virus and/or presence of antigens or antibodies for human diseases and/or presence of **drug** levels of therapeutic drugs known to be used in treatment of infectious diseases and/or presence of **drug** levels of "recreational" drugs and/or genetic testing and the step of reading biometric indicia from a label on the test. . .

SUMM . . . of infectious status of the voluntary test subject and/or presence of antigens or antibodies for human diseases and/or presence of **drug** levels of therapeutic drugs known to be used in treatment of infectious diseases and/or presence of **drug** levels of "recreational" drugs and/or genetic testing, and a computer coupled to the label reader and to the analyzer. The. . .

DETD When **drug** testing is linked to a database via a biodata key, it becomes possible for results to be registered or escrowed. . . a third party organization whereby a prospective employer may request a prospective employee to access his or her own prior **drug** test results. This arrangement does not result in liability to a prior employer of the prospective employee, because the prior. . . relevant

to the prospective employee. Privacy is assured because the prospective employee (i) can only access results from his own **drug** tests and (ii) is free to choose not to provide the biometric scan required in order to access his or. . .

DETD . . . or other indicia in samples from the test subject, (ii) drugs used to treat sexually transmissible diseases and/or (iii) "recreational" **drug** use, especially that associated with risk of acquiring communicable diseases, for example, via sharing of hypodermic needles, as desired or. . .

DETD . . . who may have expressed mutual interest in sexual activity but who may also have concerns about the infectious status and/or **drug** treatment or use status of each other. "A" optionally enters a serial number SN (block 94) via data entry device. . .

DETD . . . that in some settings, a single individual may wish to access their own data. For example, in the scenario where **drug** testing data are escrowed with a third-party agency, a prospective employer may invite a prospective employee to access the prospective employee's escrowed **drug** tests (and, desirably, dates of testing and analysis as well as test parameters, such as testing threshold levels employed to. . .

DETD . . . oral mucosal transudate. The device comprises a shaft, preferably angulated, fashioned of any suitable material such as plastic having a **pad** disposed at a first end for collection of oral mucosal transudate and including a surface disposed at a second end. . .

DETD . . . materials including antibodies from the blood vessels of the cheek and oral cavity via hypertonic saline materials included in the **pad**.

DETD . . . Goldstein et al. and apparatus for the immunoassay is described in U.S. Pat. No. 5,234,001 ("Container For Immunoassay With Frangible **Nipple**"), which patents are hereby incorporated herein for their teachings relative to oral sample collection.

DETD Preferred **pad** materials include thick, absorbent cotton paper such as product #300 manufactured by Schleicher and Schuell in Keene NH.

Preferably, the **pad** is treated with a hypertonic solution (e.g., NaCl) such that the concentration of salt in the **pad** exceeds that found in blood. Desirably, a non-specific binding agent and a preservative are also included in the **pad** material, as described by Goldstein et al. Pads of this type may be used to test for a variety of. . .

DETD In use, the test subject places the oral mucosal transudate collection device in the mouth such that the **pad** for collection of oral mucosal transudate is appropriately disposed within the oral cavity for the recommended period of time. This. . .

DETD In a second preferred embodiment, the dermatoglyphic recording **pad** comprises a waxy surface for recording fingerprints, which surface is covered with a protective layer prior to use. The protective. . . layer is removed to allow recording of the fingerprint information as the donor picks the device up to place the **pad** into the donor's mouth.

DETD In either of these embodiments, linking the results of tests done on the

oral mucosal transudate on the **pad** to the dermatoglyphic data from the fingerprint analysis tool, the same donor may retrieve the data from the tests by. . .

DETD . . . thumb meet. The oral secretion collection device usefully includes a fingerprint imprint area at an angle such the forefinger fingerprint **pad** aspect of the forefinger meets, over a wide area, the surface of the fingerprint imprint aspect of the collection device,. . .

DETD . . . is disclosed as the optimal angle between the holding aspect of the sample collection device and the plane of the **pad** for the oral mucosal transudate collection aspect of the device.

DETD Again, it will be appreciated that sensors within the oral mucosal transudate collection **pad** 352 may be employed to determine that the (i) pH, salinity etc. are appropriate for human oral mucosal transudate, (ii) temperature of the oral mucosal transudate collection **pad** 352 is appropriate to a human oral cavity and (iii) that the oral mucosal transudate are collected at the same. . .

CLM What is claimed is:
5. The apparatus of claim 1, wherein said sample collection apparatus comprises an oral **pad** treated with hypertonic saline solution, said oral **pad** for collecting oral mucosal transudate.

. . . apparatus for collecting medical specimens from a voluntary test subject, said apparatus comprising: a sample collection apparatus comprising an oral **pad** treated with hypertonic saline solution, said oral **pad** for collecting oral mucosal transudate from said test subject; a biometric data storage device, said biometric data storage device coupled. . .

. . . said biometric data storage device comprises an area disposed on a distal end of a handle coupled to said oral **pad**, said area permitting data derived from fingerprint scanning to be written thereto via a printer.

L21 ANSWER 6 OF 7 USPATFULL

AB An adapter for use with an apparatus for the control of human lactation.
The apparatus comprising a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast** and having a protrusion which extends away from the support and is positioned to align substantially with a **nipple** of a human female. The adapter comprises an attachment having a second outer surface and a second inner surface. The second outer surface has a second protrusion extending away from the second outer surface and is shaped to fit over the first protrusion. The second inner surface is positioned to align substantially with and contact a **nipple** of the human female **breast** to prevent the human female **breast** from lactating when the apparatus with the adapter is placed over the human female **breast**.

AN 1998:32762 USPATFULL

TI Adapter for use with apparatus and method for controlling human lactation

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PI US 5732714 19980331
AI US 1996-692984 19960807 (8)
RLI Continuation of Ser. No. US 1995-396704, filed on 1 Mar 1995, now abandoned which is a continuation-in-part of Ser. No. US 1992-954012, filed on 30 Sep 1992, now patented, Pat. No. US 5394889
DT Utility
FS Granted
EXNAM Primary Examiner: Brown, Michael A.
LREP Nixon, Hargrave, Devans & Doyle
CLMN Number of Claims: 18
ECL Exemplary Claim: 1
DRWN 22 Drawing Figure(s); 6 Drawing Page(s)
LN.CNT 477
TI Adapter for use with apparatus and method for controlling human lactation
AB . . . a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast** and having a protrusion which extends away from the support and is positioned to align substantially with a **nipple** of a human female. The adapter comprises an attachment having a second outer surface and a second inner surface. The. . . shaped to fit over the first protrusion. The second inner surface is positioned to align substantially with and contact a **nipple** of the human female **breast** to prevent the human female **breast** from lactating when the apparatus with the adapter is placed over the human female **breast**.
SUMM . . . teeth, and speech development, among others. Furthermore, it has been suggested that nursing mothers have a lower risk of developing **breast** cancer. **Breast** feeding has also been suggested to improve the emotional bond between mother and child.
SUMM Although **breast** feeding is enjoying renewed use, it is not without disadvantages. The outpouring of milk is known as the "let-down" or. . .
SUMM . . . be particularly problematic for working mothers who are nursing. Solutions designed to alleviate problems associated with inappropriate let-down include absorbent **breast** pads or **breast** shields that operate, essentially, as a well or reservoir to collect leaking milk. These solutions are disadvantageous because of the. . .
SUMM . . . the size of nipples for mothers swell. To ensure that milk ejection will be suppressed substantially all of the exposed **nipple** must be compressed.
SUMM . . . breastfeed and want to dry up has also been difficult. One option for stopping lactation has been the use of **drug** therapy, however the use of **drug** therapy has come under intense scrutiny because of the serious side effects these drugs have produced. The other existing option. . .
SUMM . . . a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast** and having a first protrusion which extends away from the support and is positioned to align substantially with a **nipple** of a human female. An adapter for use with the apparatus includes an attachment having a second outer surface and. . . over the first protrusion for the apparatus. The second inner surface is positioned to align substantially with and contact a **nipple** of the human female **breast** to prevent the human female **breast** from lactating when the apparatus with the adapter is placed over the human female **breast**.

SUMM . . . to prevent inopportune milk leakage in the nursing mother. The adapter enables nursing mothers to adjust the size of the **nipple** contact surface to their particular **nipple** size so that the **nipple** is covered and leakage is controlled. The apparatus and method, with or without the adapter, are also effective to stop a woman from lactating by applying constant pressure to the **nipple** until the woman dries up naturally. The apparatus and the adapter can be inexpensively constructed in a variety of shapes. . .

DRWD FIG. 1 is an exploded, perspective view of one embodiment of the apparatus of the present invention and an absorbent **breast pad**;

DRWD FIG. 2 is a front view of an absorbent **breast pad**;

DRWD FIG. 3 is a side view of an absorbent **breast pad**;

DRWD FIG. 7 is a cross-sectional side view of the apparatus, including a brassiere, placed over a human female **breast**;

DRWD FIG. 13 is an exploded, perspective view of another embodiment for the absorbent **breast pad**;

DRWD FIG. 14 is a perspective view of the absorbent **breast pad** shown in FIG. 13;

DRWD FIG. 15 is an exploded, perspective view of the apparatus, adapter, absorbent **breast pad** being positioned to be placed over a human female **breast**;

DRWD FIG. 16 is a cross-sectional, side view of the apparatus and adapter, including a brassiere and the absorbent **breast pad**, placed over a human female **breast**;

DETD FIG. 1 is an exploded, perspective view of one embodiment of the apparatus of the present invention and an absorbent **breast pad**. Apparatus 1 includes support 2 having an inner surface 3 and an outer surface 5. Inner surface 3 has a. . . which is a cross-sectional side view of one embodiment of the present apparatus, including a brassiere, placed over a human **breast**, protrusion 7 is positioned to align substantially with and contact **nipple** N of human female **breast** B. Protrusion 7 operates to depress **nipple** N, whereby **breast** B is prevented from lactating.

DETD Support 2 is shaped to conform substantially to a human female **breast**. Support 2 can, for example, be substantially circular with a concave/convex shape covering a relatively small area of **breast** B as shown in FIG. 7. Support 2 can also take a variety of other forms, substantially conforming to larger or smaller areas of **breast** B. Preferably, support 2 is constructed in a substantially circular, concave/convex form and having a radius from about 3 to. . . of the apparatus on breasts of various sizes. Most preferably, support 2 is shaped such that suction is created between **breast** B and apparatus 1 after apparatus 1 is placed over **breast** B. The suction helps to maintain the alignment of apparatus 1 with **nipple** N.

DETD . . . outer surfaces, respectively, of support 2, support 2 can be provided with holes 4 to allow air circulation around the **nipple** and areolar region of **breast** B to help prevent local irritation which commonly occurs in nursing mothers.

DETD . . . Protrusion 7 can be made from a variety of materials, as long as the material is sufficiently rigid to depress **nipple** N when **nipple** N is contacted by protrusion 7. Exemplary materials for forming protrusion 7 include any of the rigid plastics known in. . .

DETD Protrusion 7 can be any shape, so long as it is capable of depressing **nipple** N when apparatus 1 is brought into contact with

breast B and, in turn, preventing lactation. For example, protrusion 7, can be a flattened, planar surface formed in the center. . . the support and protrusion of the present invention. Protrusion 7 is preferably cylindrical, having a size approximating a human female **nipple**, as shown in FIG. 7. Most preferably, as illustrated by FIGS. 7 and 9, **nipple**-contacting surface 8 of protrusion 7 is concave to make the apparatus more comfortable for the wearer and aid in keeping. . .

DETD Preferably, absorbent **pad** 9 is placed over inner surface 3 to absorb any small amount of leakage resulting, for example, from misalignment of protrusion 7 and **nipple** N as well as any other moisture surrounding the **nipple** and areolar region. This embodiment is illustrated by FIGS. 1 and 7.

DETD As shown by FIG. 7, the above-described apparatus can be used by placing it over **breast** B and applying pressure to the apparatus sufficient to depress and, in turn, prevent milk release by **nipple** N of **breast** B. The amount of pressure need not be great and can normally be produced by the force provided when apparatus. . .

DETD . . . shapes, as described later with respect to FIGS. 18 and 21. Inner surface 36 is used to contact with the **nipple** N of the lactating woman. Adapter 30 expands the surface area which engages with the **nipple** N. The larger adapters 30 cover women who have larger nipples due to genetics or due to swelling before or after pregnancy. Lactation is only prevented if the **nipple** is substantially covered and depressed. By way of example only, **nipple** contacting surface 8 on protrusion 7 in FIG. 5 has a diameter of about 3/4", but when adapter 30 is. . .

DETD . . . catches against the inside of the cup to help keep support 44 and adapter 30 in place against the woman's **breast** B. Although only one raised ring 50 is shown, support 44 can have as may raised rings 50 on outer. . .

DETD . . . extend through support 44 between outer and inner surfaces 46 and 48 to allow air to circulate to the woman's **breast** B to prevent local irritation. The number of air holes 52 is increased from that shown for support 2 in FIGS. 4 and 6 so that even more air can circulate through to the **breast** B. Apparatus 32 and adapter 30 can be used not only to control lactation, but also to stop lactation. To. . .

DETD Referring to FIGS. 13 and 14, optional absorbent **breast pad** 58 includes four layers 60 (a-d) of absorbent material which are joined together by stitching 62 along an outside edge. . . made from cotton, although other shapes and materials could be used. If additional layers were added, then the thickness of **pad** 58 would cause adapter 30 and apparatus 32 to slip out of place, if fewer layers were used, then **pad** 58 would provide less comfort to the user.

DETD Referring to FIGS. 15 and 16, the use of apparatus 32 with adapter 30 and absorbent **breast pad** 58 is illustrated. First, if the woman's **nipple** N is larger then end 54 of protrusion 42 of support 44, then adapter 30 is selected and protrusion 40. . . adaptor 30 is placed over protrusion 42 of apparatus 32 to attach adapter 30 to apparatus 32. If the woman's **nipple** N is not inverted (as shown in FIG. 16), then an adapter 30 with a substantially concave, inner surface 36 is selected. The substantially concave, inner surface 36 surrounds the **nipple** N and areolar region and helps to keep adapter 30 in place. If the woman's **nipple** is inverted

N', as shown in FIG. 20, or flat (not shown), then an adapter 30 with a substantially flat. . .

DETD . . . 30 is in place, then brassiere 11 is put on by the woman locating apparatus 32 and adapter 30 over **breast** B and, in particular, locating substantially concave, inner surface 36 of adapter 30 against **nipple** N. Optional absorbent **breast pad** 58 may be placed between **breast** B and substantially concave, inner surface 36 of adapter 30 before or after brassiere 11 is in place. Absorbent **breast pad** 58 absorbs any small leakage or excess moisture and makes adapter 30 and apparatus 32 more comfortable against **breast** B. Once apparatus 32 and adapter 30 are in place against **breast** B, brassiere 11 applies sufficient pressure on substantially concave, inner surface 36 of adapter 30 to depress **nipple** N preventing the release of milk.

DETD . . . The substantially fiat shape for inner surface 36 is desirable for preventing lactation from woman with at least one inverted **nipple** N', as shown in FIG. 20 or flat **nipple**. With an inverted **nipple** or flat **nipple**, apparatus 32 with adapter 30 having a substantially flat, inner surface 36 is preferable over apparatus 32 with adapter 30. . . adapter 30 were used, the outer edges of concave, inner surface 36 would dig into the areolar region of the **breast**. With substantially flat, inner surface 36, the inverted **nipple** N', as shown in FIG. 20, or flat **nipple** (not shown) is compressed without undue pressure from the edge of inner surface 36 cutting into the areolar region. As. . .

DETD . . . correspond to those used in FIG. 16 and will not be described here again. In this particular embodiment, the woman's **breast** B' has an inverted **nipple** N'. Accordingly, an adapter 30 with a substantially flat, inner surface 36 is used to comfortably compress inverted **nipple** N' to prevent lactation, without applying undue pressure on the areolar region. In this particular embodiment, optional absorbent **breast pad** 58 is not used. Although adapter 30 with a substantially flat, inner surface 36 is shown, adapter 30 with a. . .

DETD . . . 36 has a substantially convex shape. The convex shape of inner surface 36 may also be used on an inverted **nipple** to apply pressure to prevent lactation, however the substantially convex shape will not stay in place against the inverted **nipple** as well as the substantially flat shape. As shown in FIG. 22, outer surface of adapter 30 in opening of. . .

CLM What is claimed is:

2. The adapter according to claim 1, wherein said **nipple** -contacting inner surface has a substantially concave shape.

. . . with an apparatus for the control of human lactation, said adapter comprising an attachment having an outer surface and a **nipple** -contacting inner surface, said outer surface having a protrusion extending away from said outer surface to an end, said protrusion having. . .

. . . with an apparatus for the control of human lactation, said adapter comprising an attachment having an outer surface and a **nipple** -contacting inner surface, said outer surface having a protrusion extending away from said outer surface to an end, said protrusion having. . .

. . . having a first outer surface and a first inner surface that is shaped to conform substantially to a human female **breast**, said first inner surface having a first protrusion extending away from said

support; providing an adapter comprising an attachment having. . . shaped to fit over said first protrusion; placing said second protrusion over said first protrusion; placing said apparatus over said **breast**; positioning said apparatus to align said second inner surface substantially with and contact said **nipple** of said **breast**; and applying pressure to said apparatus sufficient to prevent said **breast** from lactating.

11. The method according to claim 7, wherein said second inner surface is substantially the same size as said **nipple**.

12. The method according to claim 7, wherein said second inner surface is substantially larger than said **nipple**.

13. An apparatus for the control of human lactation comprising a support having a first outer surface and a first. . . said first inner surface having a first protrusion extending away from said support and positioned to align substantially with a **nipple** of said human female **breast** when said apparatus is placed over said human female **breast**, and an adapter having a second outer surface and a second inner surface, said second outer surface having a second. . . shaped to fit over said first protrusion and said second inner surface positioned to align substantially with and contact a **nipple** of said human female **breast** to prevent said human female **breast** from lactating when said apparatus is placed over said human female **breast**.

17. The apparatus according to claim 13, further comprising an absorbent **breast pad** placed on said inner surface of said support.

18. The apparatus according to claim 17, wherein said absorbent **breast pad** comprises four layers.

L21 ANSWER 7 OF 7 USPATFULL

AB An apparatus comprising a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast** and having a protrusion with a substantially flat, **nipple**-contacting surface which extends away from the support and is positioned to align substantially with and contact a **nipple** of a human female **breast** prevents a human female **breast** from lactating when placed over the **breast**. The present invention also provides a method for controlling human lactation which utilizes the present apparatus and includes the steps of placing and positioning the apparatus over the **breast** and applying pressure on the apparatus sufficient to prevent lactation.

AN 96:57217 USPATFULL

TI Apparatus and method for controlling human lactation

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PI US 5531231 19960702

AI US 1995-396921 19950301 (8)

RLI Continuation-in-part of Ser. No. US 1992-954012, filed on 30 Sep 1992, now patented, Pat. No. US 5394889
DT Utility
FS Granted
EXNAM Primary Examiner: Brown, Michael A.
LREP Nixon, Hargrave, Devans & Doyle
CLMN Number of Claims: 19
ECL Exemplary Claim: 1
DRWN 12 Drawing Figure(s); 2 Drawing Page(s)
LN.CNT 343
TI Apparatus and method for controlling human lactation
AB . . . a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast** and having a protrusion with a substantially flat, **nipple** -contacting surface which extends away from the support and is positioned to align substantially with and contact a **nipple** of a human female **breast** prevents a human female **breast** from lactating when placed over the **breast**. The present invention also provides a method for controlling human lactation which utilizes the present apparatus and includes the steps of placing and positioning the apparatus over the **breast** and applying pressure on the apparatus sufficient to prevent lactation.
SUMM . . . teeth, and speech development, among others. Furthermore, it has been suggested that nursing mothers have a lower risk of developing **breast** cancer. **Breast** feeding has also been suggested to improve the emotional bond between mother and child.
SUMM Although **breast** feeding is enjoying renewed use, it is not without disadvantages. The outpouring of milk is known as the "let-down" or. . .
SUMM . . . be particularly problematic for working mothers who are nursing. Solutions designed to alleviate problems associated with inappropriate let-down include absorbent **breast** pads or **breast** shields that operate, essentially, as a well or reservoir to collect leaking milk. These solutions are disadvantageous because of the. . .
SUMM Controlling lactation in mothers with "inverted nipples" has been particularly problematic. An inverted **nipple** is a **nipple** that does not protrude or become erect and extend away from the areolar region. Since the **nipple** is sunk into the areolar region, accessing the **nipple** to apply pressure and control or stop leakage is more difficult than with non-inverted nipples.
SUMM . . . breastfeed and want to dry up has also been difficult. One option for stopping lactation has been the use of **drug** therapy, however the use of **drug** therapy has come under intense scrutiny because of the serious side effects these drugs have produced. The other existing option. . . a need for apparatus that can effectively control and/or stop lactation in mothers, particularly those with at least one inverted **nipple**.
SUMM . . . a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast**. The inner surface has a protrusion with a substantially flat, **nipple** -contacting surface which extends away from the support and is positioned to align substantially with and contact a **nipple** of a human female **breast** when the apparatus is placed over the **breast**. In this way, the substantially flat, **nipple** contacting surface of the protrusion prevents the **breast**, even with an inverted or flat **nipple**, from lactating. The method

includes the steps of placing the apparatus over the **breast** and applying pressure on the apparatus sufficient to prevent lactation.

DRWD FIG. 1 is an exploded, perspective view of one embodiment of the apparatus of the present invention and an absorbent **breast pad**;

DRWD FIG. 2 is a front view of an absorbent **breast pad**;

DRWD FIG. 3 is a side view of an absorbent **breast pad**;

DRWD FIG. 7 is a cross-sectional side view of the apparatus, including a brassiere, placed over a human female **breast**;

DRWD FIG. 10 is a cross-sectional side view of the apparatus taken along line 10--10, including an absorbent **breast pad** and a brassiere, placed over a human female **breast**;

DRWD FIG. 11 is an exploded, perspective view of another embodiment for the absorbent **breast pad** shown in FIG. 10; and

DRWD FIG. 12 is a perspective view of the absorbent **breast pad** shown in FIG. 11.

DETD FIG. 1 is an exploded, perspective view of one embodiment of the apparatus of the present invention and an absorbent **breast pad**. Apparatus 1 includes support 2 having an inner surface 3 and an outer surface 5. Inner surface 3 has a. . . which is a cross-sectional side view of one embodiment of the present apparatus, including a brassiere, placed over a human **breast**, protrusion 7 is positioned to align substantially with and contact **nipple** N of human female **breast** B. Protrusion 7 operates to depress **nipple** N, whereby **breast** B is prevented from lactating.

DETD Support 2 is shaped to conform substantially to a human female **breast**. Support 2 can, for example, be substantially circular with a concave/convex shape covering a relatively small area of **breast** B as shown in FIG. 7. Support 2 can also take a variety of other forms, substantially conforming to larger or smaller areas of **breast** B. Preferably, support 2 is constructed in a substantially circular, concave/convex form and having a radius from about 3 to. . . of the apparatus on breasts of various sizes. Most preferably, support 2 is shaped such that suction is created between **breast** B and apparatus 1 after apparatus 1 is placed over **breast** B. The suction helps to maintain the alignment of apparatus 1 with **nipple** N.

DETD . . . outer surfaces, respectively, of support 2, support 2 can be provided with holes 4 to allow air circulation around the **nipple** and areolar region of **breast** B to help prevent local irritation which commonly occurs in nursing mothers.

DETD . . . Protrusion 7 can be made from a variety of materials, as long as the material is sufficiently rigid to depress **nipple** N when **nipple** N is contacted by protrusion 7. Exemplary materials for forming protrusion 7 include any of the rigid plastics known in. . .

DETD Protrusion 7 can be any shape, so long as it is capable of depressing **nipple** N when apparatus 1 is brought into contact with **breast** B and, in turn, preventing lactation. For example, protrusion 7, can be a flattened, planar surface formed in the center. . . the support and protrusion of the present invention. Protrusion 7 is preferably cylindrical, having a size approximating a human female **nipple**, as shown in FIG. 7. Most preferably, as illustrated by FIGS. 5 and 7, **nipple**-contacting surface 8 of protrusion 7 is concave to make the apparatus more comfortable for the wearer and aid in keeping. . .

DETD Preferably, absorbent **pad** 9 is placed over inner surface 3 to absorb any small amount of leakage resulting, for example, from misalignment of protrusion 7 and **nipple** N, as well as any other moisture surrounding the **nipple** and areolar region. This embodiment is illustrated by FIGS. 1 and 7.

DETD As shown by FIG. 7, the above-described apparatus can be used by placing it over **breast** B and applying pressure to the apparatus sufficient to depress and, in turn, prevent milk release by **nipple** N of **breast** B. The amount of pressure need not be great and can normally be produced by the force provided when apparatus. . .

DETD . . . for apparatus 32 is illustrated. Apparatus 32 includes support 34 which is shaped to substantially conform to a human female **breast** and has outer surface 30, an inner surface 36 (shown in FIG. 10), a raised ring 38, and a plurality. . .

DETD . . . raised ring 38 catches against the inside of the cup to help keep support 34 in place against the woman's **breast** B'. Although only one raised ring 38 is shown, support 34 can have as may raised rings 30 on outer. . .

DETD . . . extend through support 34 between outer and inner surfaces 30 and 36 to allow air to circulate to the woman's **breast** B1 to prevent local irritation. The number of air holes 40 is increased from that shown for support 2 in FIGS. 4 and 6 so that even more air can circulate through to the **breast** B'. Apparatus 32 can be used not only to control lactation, but also to stop lactation. To stop lactation, apparatus. . .

DETD Referring to FIG. 10, a cross-sectional view of support 34 taken along line 10--10 in FIG. 9, with an absorbent **breast pad** 42 and brassiere 11, placed over a human female **breast** B' are illustrated. Outer surface 30 of support 34 has a convex shape and inner surface 36 of support 34. . . through friction helps to hold support 34 in place. A protrusion 41 extends from inner surface 36 out to a **nipple** contacting surface 43 which in this particular embodiment is substantially flat and operates to depress **nipple** N' to prevent lactation. Preferably, protrusion 41 is integrated with support 34, although protrusion 41 could be produced separately and. . . cylindrical shape with a cross-sectional area which is the same as or larger then the size of a human female **nipple**, although the shape and size of protrusion 41 can vary as desired. In this particular embodiment, protrusion 41 has a. . . Protrusion 41 can be made from a variety of materials, as long as the material is sufficiently rigid to depress **nipple** N' when **nipple** N' is contacted by protrusion 41. Exemplary materials for forming protrusion 41 include any of the rigid plastics known in the art or sufficiently rigidized rubber. The optional absorbent **pad** 42 is located between **nipple** contacting surface 43 of projection 41 and **nipple** N' to absorb any small leakage or excess moisture and to make support 34 more comfortable against **breast** B'.

DETD Referring to FIGS. 11-12, absorbent **breast pad** 42 is constructed with four layers 44(a-d) of absorbent material which are joined together by stitches 46 along an outside. . . from cotton, although other shapes and materials could be used. If additional layers were added, then the thickness of the **pad** 42 would cause

protrusion 41 for support 34 to slip out of place. If fewer layers were used, then the **pad** 42 would provide less comfort to the user.

DETD Unlike apparatus 1, apparatus 32 is designed to be used on a **breast** B' with an inverted **nipple** N' as shown in FIG. 10. To use apparatus 32, outer surface 30 of support 34 is placed inside

and. . . 11. Once apparatus 32 is in place, then brassiere 11 is put on by the woman locating apparatus 32 over **breast** B' and, in particular, locating substantially flat, **nipple**-contacting surface 43 against **nipple** N'. Optional absorbent **pad** 42 may be placed between **breast** B' and substantially flat, **nipple** contacting surface 43 of protrusion 41 before or after brassiere 11 is in place. Raised ring 38 holds support 30 in place against brassiere 11 because of friction. Once apparatus 32 is in place against **breast** B', brassiere 11 applies sufficient pressure on substantially flat, **nipple** contacting surface 43 of protrusion 41 to depress **nipple** N' preventing the release of milk.

DETD When a woman has an inverted **nipple**, apparatus 32 with substantially flat, **nipple** contacting surface 43 is preferable over apparatus 1 with concave, **nipple** contacting surface. If the latter apparatus were used, the outer edges of the concave, **nipple** contacting surface would dig into the areolar region of the **breast**. With the substantially flat, **nipple** contacting surface 43, inverted **nipple** N' is compressed without undue pressure from the edge of the **nipple** contacting surface 43 cutting into the areolar region.

CLM What is claimed is:

. . . a support having an outer surface and an inner surface that is shaped

to conform substantially to a human female **breast**, said inner surface having a substantially rigid protrusion with a substantially flat, **nipple**-contacting surface extending away from said support and positioned to align substantially with and contact a **nipple** of said human female **breast** when said apparatus is placed over said human female **breast**, whereby said protrusion substantially prevents said human female **breast** from lactating.

3. The apparatus according to claim 1, wherein said protrusion is substantially the same size as said **nipple**.

4. The apparatus according to claim 1, wherein said protrusion is substantially larger than said **nipple**.

10. The apparatus according to claim 1, further comprising an absorbent **breast pad** placed on said inner surface of said support.

11. The apparatus according to claim 10, wherein said absorbent **breast pad** comprises four layers.

. . . having an outer convex surface and an inner concave surface that is shaped to conform substantially to a human female **breast**, said inner surface having a substantially flat protrusion extending away from

said support and positioned to align substantially with and contact a **nipple** of said human female **breast** when said apparatus is placed over said human female **breast**, whereby said protrusion substantially prevents said human female **breast**

from lactating.

. . . a support having an outer surface and an inner surface that is shaped to conform substantially to a human female **breast**, said inner surface having a substantially rigid protrusion with a substantially flat, **nipple**-contacting surface extending away from said support and positioned to align substantially with and contact a **nipple** of said human female **breast** when said apparatus is placed over said human female **breast**, whereby said protrusion substantially prevents said human female **breast** from lactating; placing said apparatus over said **breast**; positioning said apparatus to align said protrusion substantially with and contact said **nipple** of said **breast**; and applying pressure to said apparatus sufficient to prevent said **breast** from lactating.

16. The method according to claim 14, wherein said protrusion is substantially the same size as said **nipple**.

17. The method according to claim 14, wherein said protrusion is substantially larger than said **nipple**.

=> d l21 4-7 bib

L21 ANSWER 4 OF 7 USPATFULL
AN 2000:30651 USPATFULL
TI Disposable **breast pad**
IN Coburn, Shonda L., 1020 11th St., Marysville, CA, United States 95901
PI US 6036577 20000314
AI US 1998-25296 19980218 (9)
DT Utility
FS Granted
EXNAM Primary Examiner: Calvert, John J.; Assistant Examiner: Hoey, Alissa L.
LREP Litman, Richard C.
CLMN Number of Claims: 6
ECL Exemplary Claim: 1
DRWN 4 Drawing Figure(s); 3 Drawing Page(s)
LN.CNT 186

L21 ANSWER 5 OF 7 USPATFULL
AN 1999:27390 USPATFULL
TI Method, apparatus and system for verification of human medical data
IN Beecham, James E., 8820 Cortile Dr., Las Vegas, NV, United States 89134
PI US 5876926 19990302
AI US 1997-910062 19970806 (8)
RLI Continuation-in-part of Ser. No. US 1996-686211, filed on 23 Jul 1996
DT Utility
FS Granted
EXNAM Primary Examiner: Stucker, Jeffrey
LREP Seed & Berry LLP
CLMN Number of Claims: 17
ECL Exemplary Claim: 1
DRWN 16 Drawing Figure(s); 10 Drawing Page(s)
LN.CNT 1537

L21 ANSWER 6 OF 7 USPATFULL
AN 1998:32762 USPATFULL
TI Adapter for use with apparatus and method for controlling human lactation
IN Morrissey, Gerald, 3 Lake View Cir., Skaneateles, NY, United States 13152
Morrissey, Suzanne, 3 Lake View Cir., Skaneateles, NY, United States 13152
PI US 5732714 19980331
AI US 1996-692984 19960807 (8)
RLI Continuation of Ser. No. US 1995-396704, filed on 1 Mar 1995, now abandoned which is a continuation-in-part of Ser. No. US 1992-954012, filed on 30 Sep 1992, now patented, Pat. No. US 5394889
DT Utility
FS Granted
EXNAM Primary Examiner: Brown, Michael A.
LREP Nixon, Hargrave, Devans & Doyle
CLMN Number of Claims: 18
ECL Exemplary Claim: 1
DRWN 22 Drawing Figure(s); 6 Drawing Page(s)
LN.CNT 477

L21 ANSWER 7 OF 7 USPATFULL
AN 96:57217 USPATFULL
TI Apparatus and method for controlling human lactation
IN Morrissey, Gerald, 3 Lake View Cir., Skaneateles, NY, United States 13152
Morrissey, Suzanne, 3 Lake View Cir., Skaneateles, NY, United States 13152
PI US 5531231 19960702
AI US 1995-396921 19950301 (8)
RLI Continuation-in-part of Ser. No. US 1992-954012, filed on 30 Sep 1992, now patented, Pat. No. US 5394889
DT Utility
FS Granted
EXNAM Primary Examiner: Brown, Michael A.
LREP Nixon, Hargrave, Devans & Doyle
CLMN Number of Claims: 19
ECL Exemplary Claim: 1
DRWN 12 Drawing Figure(s); 2 Drawing Page(s)
LN.CNT 343

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